

# **EXHIBIT 14**

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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & )  
JOHNSON TALCUM POWDER )  
PRODUCTS MARKETING )  
SALES PRACTICES AND ) MDL 16-2738  
PRODUCT LIABILITY ) (FLW) (LHG)  
LITIGATION )  
\_\_\_\_\_)  
THIS DOCUMENT )  
PERTAINS TO ALL CASES )

WEDNESDAY, DECEMBER 19, 2018

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- - -

Videotaped deposition of Laura Plunkett, Ph.D., DABT, held at the Four Seasons Hotel, 999 North 2nd Street, St. Louis, Missouri, commencing at 9:12 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri & Kansas Certified Court Reporter.

- - -

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1                   VIDEOGRAPHER: We are now on  
2                   the record.

3                   My name is Jacob Arndt. I'm a  
4                   videographer for Golkow Litigation  
5                   Services.

6                   Today's date is December 19,  
7                   2018, and the time is 9:12 a.m.

8                   This deposition is being held  
9                   in St. Louis, Missouri, In Re: Johnson  
10                  & Johnson Products Marketing Sales  
11                  Practices, for the United States  
12                  District Court for the District of  
13                  New Jersey.

14                  The deponent is Dr. Laura  
15                  Plunkett.

16                  Will counsel please identify  
17                  themselves?

18                  MR. MEADOWS: Ted Meadows for  
19                  plaintiffs.

20                  MS. PARFITT: Michelle Parfitt  
21                  for the plaintiffs.

22                  MR. BEATTIE: Ryan Beattie for  
23                  plaintiffs.

24                  MR. TISI: Chris Tisi for  
25                  plaintiffs.

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1 MR. GOLOMB: Richard Golomb for  
2 plaintiffs.

3 MR. LOCKE: Tom Locke for the  
4 Personal Care Products Council.

5 MS. TINSLEY: Caroline Tinsley  
6 for PTI Union, LLC, and PTI Royston,  
7 LLC.

8 MR. SULLIVAN: Ryan Sullivan  
9 for Imerys.

10 MS. BOCKUS: Jane Bockus for  
11 Imerys.

12 MR. SMITH: William Smith for  
13 Johnson & Johnson.

14 MS. BRANSCOME: Kimberly  
15 Branscome for Johnson & Johnson.

16 VIDEOGRAPHER: Thank you.

17 The court reporter is Carrie  
18 Campbell and will now swear in the  
19 witness.

20 LAURA PLUNKETT, Ph.D., DABT,  
21 of lawful age, having been first duly sworn  
22 to tell the truth, the whole truth and  
23 nothing but the truth, deposes and says on  
24 behalf of the Defendant Johnson & Johnson, as  
25 follows:

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1 DIRECT EXAMINATION

2 QUESTIONS BY MS. BRANSCOME:

3 Q. All right. Good morning,  
4 Dr. Plunkett. I introduced myself right  
5 before we started, but my name is Kimberly  
6 Branscome, and I am here on behalf of Johnson  
7 & Johnson.

8 Is it your understanding today  
9 that you are giving your deposition for the  
10 purpose of a Daubert analysis in the MDL  
11 related to Johnson's baby powder?

12 A. That's my understanding, yes.

13 (Plunkett Exhibit 1 marked for  
14 identification.)

15 QUESTIONS BY MS. BRANSCOME:

16 Q. I want to start by handing you  
17 what I will mark as Plunkett Deposition  
18 Exhibit 1.

19 Do you recognize the document  
20 that I just handed you?

21 A. Yes.

22 Q. Okay. Have you seen this  
23 document before?

24 A. Yes.

25 Q. All right. When was this

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1 document provided to you?

2 A. Either earlier this -- this  
3 week or late last week. I don't recall if it  
4 was Friday or Monday.

5 Q. Okay. For the purposes of the  
6 record, could you just identify what the  
7 document is that I just handed you as  
8 Plunkett Deposition Exhibit Number 1?

9 A. It's a notice of oral and  
10 videotaped deposition for myself, dated -- I  
11 don't see the date, but probably on the very  
12 last -- do you need that or just -- is that  
13 enough of an identification?

14 Q. That's all right.

15 Now, contained within the  
16 deposition notice there is a reference to a  
17 request for materials that are identified in  
18 more detail in Schedule A.

19 Do you see that?

20 A. Yes.

21 Q. Have you reviewed Schedule A?

22 A. Yes.

23 Q. Did you bring any documents  
24 with you in response to the request in  
25 Schedule A?

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1           A.       The only thing that I believe  
2       that I had to bring that had not already been  
3       provided was additional billing since the  
4       time of my last deposition.

5           Q.       Okay. And is it my  
6       understanding that the documentation related  
7       to additional billing that you have done  
8       since your prior deposition was produced  
9       yesterday at the deposition in the Forrest  
10      case?

11          A.       That's correct.

12          Q.       All right. And the information  
13       contained in the documents produced at the  
14       Forrest deposition yesterday, do those  
15       contain an up-to-date record of the billing  
16       that you have submitted for your work in  
17       connection with the litigation against  
18       Johnson & Johnson?

19          A.       Yes, with the understanding  
20       that I haven't submitted a bill for December  
21       yet.

22          Q.       Okay. How much time have you  
23       spent working in connection with your  
24       opinions in the case against Johnson &  
25       Johnson related to its baby powder in the

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1 month of December?

2 A. So I'm -- on all the cases that  
3 I am involved in that are pending, not just  
4 this deposition?

5 Q. I'll ask first all cases and  
6 then we'll narrow it to the deposition.

7 A. So in all --

8 Q. I mean to the MDL, I'm sorry.

9 A. Okay. So in all cases this  
10 month, probably eight hours so far, maybe  
11 ten.

12 Q. Does that include the time that  
13 you've spent attending deposition?

14 A. No, that's not including  
15 yesterday's deposition time. I apologize. I  
16 forgot about that.

17 Q. And how much of the eight to  
18 ten hours that you have spent this month  
19 working on these cases against Johnson &  
20 Johnson, setting aside the time you spent in  
21 deposition yesterday, relate to the MDL  
22 specifically?

23 A. So it will probably be  
24 billed -- it will be one bill for the  
25 preparation time because the prep overlapped,

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1 but I'll bill separately for the time I spent  
2 yesterday right before the deposition and  
3 then at the deposition, so...

4 Q. What did you do to prepare for  
5 your deposition today?

6 A. I reviewed my reports, the  
7 three reports that I filed in the litigation.  
8 I had a meeting with attorneys on Monday, and  
9 then we had a short meeting yesterday evening  
10 because some attorneys arrived that were not  
11 here on Monday.

12 And essentially went through  
13 some of the documents that -- went through  
14 some of the documents that I had cited in the  
15 report in certain paragraphs, just to refresh  
16 my memory of what they were. So if you want  
17 me to tell you which paragraphs, I can do  
18 that.

19 Q. I will in just a moment. Okay.

20 A. Want me to repeat that? I'm  
21 sorry.

22 Q. That's all right.

23 Dr. Plunkett, you referenced  
24 the fact that you reviewed specific  
25 paragraphs of your expert reports in

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1 preparation for today's deposition.

2 Could you identify those  
3 paragraphs for me?

4 And it's helpful to you, we can  
5 go ahead and mark your three expert reports,  
6 if you're referring to all three.

7 A. I'm going to refer just to the  
8 MDL report because that's what we're here to  
9 talk about. I mean, if you want to talk  
10 about what I did to get ready for yesterday  
11 separately or --

12 MR. MEADOWS: Might be helpful  
13 to go ahead and mark them.

14 MS. BRANSCOME: Why don't we go  
15 ahead and just mark the three reports,  
16 and then we can walk through.

17 (Plunkett Exhibits 2, 3 and 4  
18 marked for identification.)

19 QUESTIONS BY MS. BRANSCOME:

20 Q. So, Dr. Plunkett, do you have a  
21 copy of your three reports in front of you?

22 A. Yes, I do.

23 Q. Do those contain any markings,  
24 highlightings or flags?

25 A. No, they don't.

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1 Q. Okay. Do you mind if we mark  
2 your copies as the official records?

3 A. No, that's fine.

4 Q. So we will mark -- well, let's  
5 do this in chronological order. So I am  
6 marking as Plunkett Deposition Exhibit  
7 Number 2 the expert report of Dr. Plunkett  
8 dated October 5, 2016.

9 Could you confirm,  
10 Dr. Plunkett, that that's what I marked as  
11 Deposition Exhibit Number 2?

12 A. Yes, it is.

13 Q. And then we will mark as  
14 Deposition Exhibit Number 3 supplemental  
15 expert report of Dr. Laura Plunkett dated  
16 August 29, 2018.

17 Dr. Plunkett, could you confirm  
18 that I marked that as Exhibit Number 3?

19 A. Yes, that's correct.

20 Q. And then Exhibit Number 4, we  
21 will mark the expert report dated  
22 November 16, 2018, by Dr. Plunkett that was  
23 produced in the MDL.

24 Could you confirm that I marked  
25 that as Deposition Exhibit Number 4?

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1           A.       Yes, that's correct.

2           Q.       All right. And so now back to  
3     the question of you referenced the fact that  
4     you looked at specific paragraphs of your  
5     expert report in preparation for today's  
6     deposition. If you could, using Deposition  
7     Exhibit Number 4, identify which paragraphs  
8     you looked at specifically in preparation for  
9     the deposition.

10          A.       So it wasn't the paragraphs.

11          There were certain documents in paragraphs,  
12     so that's what I was referring to, so...

13               So starting in paragraph 38  
14     where I'm talking about sort of the timeline  
15     of information about human health hazards and  
16     talc dust. So I just went back and refreshed  
17     on a few of the older papers.

18               I looked again at the patent  
19     documents that are cited in the first bullet.

20               I looked again at a paper by  
21     Eberl, 1948, which is in the last bullet.  
22     The patent documents are also there as well.

23               And that -- so that would be  
24     all I pulled in that paragraph.

25               I believe that those documents

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1 are also cited in paragraph 39 as well, some  
2 of those same ones that are...

3                   And then in Section 5 of my  
4 report where I'm talking about exposure, I  
5 looked again at Parmley and Woodruff. I  
6 looked again at Vetner and Iturrulde and Egli  
7 and Newton last night.

8                   And the only other thing I  
9 looked at is not cited in this report because  
10 it came out after the report was filed, and  
11 that was -- and I did bring a copy of that.  
12 That was the risk assessment that was done in  
13 Canada. Some people refer to it as -- by the  
14 first author's last name, Taher, T-a-h-e-r.  
15 And I may be pronouncing that wrong, but...

16                   (Plunkett Exhibit 5 marked for  
17 identification.)

18 QUESTIONS BY MS. BRANSCOME:

19                   Q. All right. And I see that you  
20 brought a copy of that document with you.  
21 Just for the purposes of the record, let's  
22 mark that as Plunkett Deposition Exhibit  
23 Number 5.

24                   Are there any markings,  
25 highlightings or notations on that document?

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1 A. No, there's not.

2 And then the other document I  
3 looked at that was not cited in the report,  
4 there is a printout from the government of  
5 Canada website that talks about some  
6 statements on talc, and so I printed that out  
7 as well. This was published at the same time  
8 that the risk assessment was published.

9 (Plunkett Exhibit 6 marked for  
10 identification.)

11 QUESTIONS BY MS. BRANSCOME:

12 Q. All right. We'll mark that for  
13 purposes of the record as Plunkett Deposition  
14 Exhibit Number 6. We might come back to  
15 those documents.

16 So returning briefly to the  
17 deposition notice and the requests in  
18 Schedule A, the billing information you  
19 produced yesterday and then we just discussed  
20 additional information with respect to that,  
21 are there any other documents that you have  
22 in your possession that are responsive to  
23 requests identified in Schedule A that have  
24 not been produced?

25 A. I don't believe so, no.

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1     Everything -- I do believe that there were  
2     some objections filed to this, so there's  
3     some things that I did not provide based on  
4     that.

5                         Some of the things I don't  
6     have, too. I think you asked for -- maybe  
7     you didn't ask for that. Usually people ask  
8     for copies of old depositions, and I don't  
9     keep those. And maybe you didn't ask for  
10    that, but that's usually a request.

11                        Let me see.

12                       Q.     Okay. Now, you mentioned that  
13    you met with attorneys on Monday. And who  
14    was present at that meeting?

15                       A.     So on Monday it was  
16    Mr. Meadows, sitting here. Ms. Tucker,  
17    Mr. Beattie, were at the meeting on Monday.

18                       Q.     All right. And how long did  
19    that meeting last?

20                       A.     Probably six hours, I guess,  
21    six hours with them, and then I also did some  
22    other work on my own, but...

23                       Q.     Okay. And then you mentioned  
24    that you had another meeting last night.

25                       Who was present at that

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1 meeting?

2 A. So that was probably about an  
3 hour, and that would have been Mr. Tisi -- or  
4 maybe two hours. Mr. Tisi joined us  
5 yesterday afternoon. And Mr. Golomb, too,  
6 I'm sorry.

7 Q. All right. Okay. Now, looking  
8 at the three reports that you have produced  
9 in the litigation involving Johnson's baby  
10 powder, I wanted to get an understanding of  
11 how those three reports relate to one  
12 another.

13 So you have the first report  
14 that you produced that was dated October 5,  
15 2016. I believe that was originally produced  
16 in the Uhl case; is that correct?

17 A. I'm not sure the name of the  
18 first case, but it was in the -- some of the  
19 St. Louis cases, yes.

20 Q. All right. And when did you  
21 begin work on that report?

22 A. You'd have to look at my  
23 billing record, which I know was an exhibit  
24 to yesterday's deposition. I believe they  
25 started in 2015.

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1           Q.       All right. And then you  
2 produced a supplemental report earlier this  
3 year, on August 29, 2018, and that's been  
4 marked as Deposition Exhibit Number 3,  
5 correct?

6           A.       Yes.

7           Q.       When did you begin work on the  
8 supplemental report that you produced at the  
9 end of August in 2018?

10          A.       I want to say -- let's see. I  
11 want to say sometime in the summer. Maybe as  
12 early as May, but I believe May -- May, June  
13 time frame of 2018.

14                 My billing would reflect that,  
15 so, again, we can pull my billing. And I  
16 would have called it preparation of the  
17 supplemental report in my billing.

18          Q.       Okay. Why did you choose to  
19 draft a supplemental expert report?

20          A.       So over the time I had worked  
21 on different trials here in St. Louis  
22 particularly, additional documents that were  
23 not cited in my original report became  
24 reliance materials based on their  
25 presentation at trial. So there were enough

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1 of those that I thought it was important to  
2 add to the original report with additional  
3 documents that I had reviewed over time.

4 Since October of 2016 through,  
5 let's say, the summer of 2018, there were a  
6 variety of additional documents that I had --  
7 I had seen.

8 It was also my understanding  
9 that during that time period Johnson &  
10 Johnson had provided additional documents  
11 that weren't provided or available to me in  
12 2016, so additional discovery that was now  
13 available to look at. So some of this is a  
14 matter of additional evidence that wasn't  
15 available when I wrote my initial -- my  
16 initial report.

17 Q. All right. Now when you say  
18 the additional documents became reliance  
19 materials in trial, what do you mean by that?

20 A. So additional documents that we  
21 refer to in trial that I use to support  
22 opinions that weren't necessarily  
23 specifically cited within the body of my  
24 report or described within the body of my  
25 report. They were likely on my larger

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1 reliance list, but they weren't things that  
2 were cited.

3 In other words, if you look at  
4 my original report in -- when I say the body,  
5 the paragraphs. I always put a reference  
6 list and then I'll have Bates numbers. So  
7 during trial, things that were from my larger  
8 reliance list that weren't specifically  
9 discussed in my report became support for  
10 different opinions that -- based on questions  
11 at trial.

12 Q. Okay. When you say these were  
13 documents that "we" refer to at trial, you're  
14 referring to yourself and attorneys  
15 representing the plaintiffs?

16 A. Yes, that's correct.

17 Q. Okay. And understanding that  
18 the purpose of today's deposition is focused  
19 specifically on the MDL, then you produced a  
20 report specific to the MDL on November 16,  
21 2018, that we've marked as Exhibit 4,  
22 correct?

23 A. Yes.

24 Q. When did you begin work on the  
25 report that you produced specifically in the

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1 MDL?

2 A. Sometime right after -- I would  
3 say early fall of 2018, sometime after  
4 this -- the supplemental report was filed.  
5 Probably right after that.

6 Q. Okay. So is it fair to say  
7 that you began work on your MDL report after  
8 completing the supplemental expert report  
9 that has been marked as Exhibit 3?

10 A. Yes, that's correct.

11 Q. Okay. Who was involved in the  
12 drafting of the report that's been identified  
13 as Exhibit 4?

14 MR. MEADOWS: Objection. Hang  
15 on a second.

16 Are you asking about  
17 communications between attorneys and  
18 Dr. Plunkett?

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Dr. Plunkett, none of the  
21 questions I will ask you here today are  
22 intended to elicit information that's  
23 protected by the attorney-client privilege.

24 So setting that aside, anything  
25 that you understand to be privileged, I can

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1 ask who the -- who was involved in the  
2 drafting of the report that was produced in  
3 the MDL?

4 MR. MEADOWS: Hold on just one  
5 second.

6 Ask the question one more time.  
7 I want to make sure we're not  
8 venturing into attorney work product  
9 realm here.

10 QUESTIONS BY MS. BRANSCOME:

11 Q. Dr. Plunkett, do you consider  
12 the report that you have issued in the MDL  
13 which is identified as Exhibit 4 to be  
14 attorney work product?

15 MR. MEADOWS: Objection. Don't  
16 answer that. That calls for a legal  
17 conclusion, and at this point I'm  
18 going to instruct you not to answer  
19 questions about how the report came  
20 into be.

21 MS. BRANSCOME: Are you  
22 instructing her to refuse to answer  
23 any questions that involve the  
24 development of her expert report?

25 MR. MEADOWS: I'm instructing

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1                   her not to answer your last question.

2       QUESTIONS BY MS. BRANSCOME:

3                   Q.         Are you following your  
4       attorney's instructions, Dr. Plunkett?

5                   A.         Yes.

6                   MS. BRANSCOME: At this point I  
7       would like to go off the record,  
8       please.

9                   VIDEOGRAPHER: Okay. We are  
10      going off the record at 9:30 a.m.

11                  (Off the record at 9:30 a.m.)

12                  VIDEOGRAPHER: We are back on  
13      the record at 9:32 a.m.

14       QUESTIONS BY MS. BRANSCOME:

15                  Q.         Dr. Plunkett, other than  
16       attorneys, if attorneys were involved -- I am  
17       not asking questions about that -- were there  
18       any individuals who assisted you in preparing  
19       the report that has been marked as Exhibit 4?

20                  A.         There was no one that actually  
21       assisted in writing the report. I do -- when  
22       I did my literature searches, I had my  
23       husband help me retrieve articles that I  
24       identified for retrieval, but certainly there  
25       was no -- he doesn't participate in the

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1 actual review of articles or in drafting of  
2 the report. That's all my work.

3 Q. Okay. And when you say that  
4 your husband retrieved articles, was this  
5 simply -- what information did you provide  
6 him in order to enable him to retrieve a  
7 particular article?

8 A. So we use a service in Houston  
9 called Loansome Doc, which is affiliated with  
10 our local medical library system and also  
11 with the National Library of medicine and NIH  
12 libraries. So I give him an online search  
13 that I put into a clipboard. He takes that,  
14 makes the request or retrieves -- some of  
15 them will be free, and so he'll actually go  
16 to the websites for the -- and then put them  
17 into a folder for me.

18 So he does that physical part  
19 of it through the computer, but he doesn't --  
20 he doesn't do the searches or decide which  
21 ones to retrieve. I do that.

22 Q. Okay. Did you have any  
23 discussions with your husband about the  
24 substantive content of the report that's  
25 identified as Exhibit 4?

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1                   A.           No.

2                   Q.           Does he do any evaluation --  
3       for example, if you were to provide him a  
4       search and it generates multiple documents by  
5       a given author, does he identify additional  
6       articles that you might want to consider?

7                   A.           Only -- he has done that, but  
8       only with the streams of letters to the  
9       editor. So I ask him always if I'm pulling  
10      an article. Happens a lot at the New England  
11      Journal of Medicine or some of the other  
12      medical journals where there's pretty active  
13      letter to the editor correspondence that  
14      happens.

15                  So I always say to him, "If  
16      there's any citation to this through the  
17      letter to the editor comments, would you  
18      please retrieve those," and so he will do  
19      that search to look for that.

20                  Q.           Okay.

21                  A.           And I'm not sure that that  
22      happened in any of these articles, but I'm  
23      talking my general process that we use.

24                  Q.           Okay. In terms of the  
25      relationship of the three reports that have

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1      been marked as Exhibits 2, 3 and 4 to each  
2      other, what is your -- what is your position  
3      with respect to opinions that you have stated  
4      or language you have used in Exhibits 2 and 3  
5      that may not appear in Exhibit 4?

6            A.       I don't think I understand what  
7      your -- what you mean by my position. Are  
8      you asking --

9                    MS. PARFITT: And I'll object  
10                  to that question.

11                  THE WITNESS: Are you asking me  
12                  to describe -- I mean, I could  
13                  describe for you the overlap. I mean,  
14                  there's not complete overlap. Is that  
15                  what you're asking me or --

16          QUESTIONS BY MS. BRANSCOME:

17            Q.       I am. Why don't you take a  
18      shot at it and then I may narrow my question,  
19      but I'm just trying to understand how the  
20      reports relate to one another.

21                  MR. MEADOWS: Objection.

22                  THE WITNESS: So they relate to  
23                  each other, I would say, based on  
24                  timing first, because obviously the  
25                  first report was two years ago, and

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1           then many more documents. So that's  
2           how the 1 and 2 relate -- or Exhibit 2  
3           and 3 relate to each other.

4           In the MDL litigation, I was  
5           asked to address very specific topics  
6           and things because there's a -- it's a  
7           different -- I don't know all of them,  
8           but there's a different set of experts  
9           that work in different litigations.

10          So my role in the MDL, I  
11          believe, is set out based on this  
12          report, whereas in the original  
13          reports I may have had -- I did have a  
14          broader role in some of those cases.

15          QUESTIONS BY MS. BRANSCOME:

16          Q.        Okay. Can you describe for me  
17          your understanding of your role in the MDL?

18          A.        It's my understanding that I  
19          have been asked to provide opinions related  
20          to the -- generally the toxicology of talcum  
21          powder products, including all the individual  
22          constituents that make up that product; to  
23          look historically back in time about what was  
24          known and when about the toxic effects of  
25          talc and different constituents within talc.

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1 And that was sort of the -- that's been --  
2 I consider that sort of the meat of what I've  
3 been asked to do.

4 But separate from that, another  
5 part important part of my testimony or things  
6 I was asked to provide was an overview of the  
7 regulatory process for cosmetics and then the  
8 information that accumulated scientifically,  
9 how that related to what a company is  
10 required to do under the regulations in order  
11 to provide consumers with appropriate  
12 information about the safety of the product.  
13 So kind of the regulatory opinions, I guess  
14 you want to call it, that area.

15 I have sections on that, and I  
16 think you can see that by the different  
17 sections in my report where I set out  
18 different general topics.

19 And then I was also asked to  
20 address some of the issues related to how the  
21 information on the safety of talc has been  
22 disseminated publicly and also based on my  
23 review of different internal company  
24 documents, both from Johnson & Johnson -- or  
25 from Johnson & Johnson, Imerys, as well as

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1       the PCPC, which is the Personal Care Products  
2       Council, formerly known as the CTFA, to look  
3       at those interactions and how those companies  
4       set about to influence the process around the  
5       safety assessment of talc over the years. So  
6       different activities that happened with  
7       respect to the IS RTP meetings in the '90s,  
8       with respect to the NTP process at different  
9       points in time.

10                  The CIR process, I think I  
11       cover, and I also talk a little bit about  
12       IARC, I believe, as well.

13                  So the interactions of the  
14       industry with the science and then how that  
15       science ends up getting described within --  
16       either to regulators or to bodies that are  
17       reviewing the science related to the  
18       products.

19                  Q.        You mentioned as one of the  
20       categories that you were asked to opine about  
21       in the MDL that you were looking to set about  
22       the influence that companies may have exerted  
23       over the regulatory process or PCPC.

24                  When you began that analysis,  
25       did you start with the predicate belief that

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1 the companies had, in fact, influenced the  
2 regulators or PCPC?

3 MR. MEADOWS: Objection.

4 THE WITNESS: Not in my -- not  
5 when I first started this process. So  
6 that is -- those opinions actually go  
7 back into my original report. So  
8 that's not something, I don't believe,  
9 that was not covered in my original  
10 report or even in my supplemental  
11 report. I just have different -- some  
12 additional documents that I have  
13 reviewed.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. Okay.

16 A. And this is something when I  
17 first evaluated the case and first started  
18 looking at the documents, those are opinions  
19 that I had formed based on my review.

20 Certainly by the time I drafted  
21 the MDL report, I think if you listened to  
22 my -- read my trial testimony, you understand  
23 I had those opinions at the time I started  
24 writing this report.

25 Q. Now, what I'd like to

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1 understand next is, are there -- of the  
2 topics that you just identified that you  
3 understand that you're offering opinions  
4 about in the MDL, which, if any, of those  
5 topics are in your view new as compared to  
6 the opinions that you have offered that are  
7 contained in Exhibits 2 and 3?

8 MS. PARFITT: Objection.

9 THE WITNESS: So I don't think  
10 any of the MDL opinions are new.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. Okay.

13 A. I think that they may have --  
14 they may -- they may cite to additional  
15 documents that haven't been cited to in the  
16 first two reports, but I believe there's a  
17 significant overlap even on the documents  
18 that are cited.

19 Q. And you mentioned that your  
20 role in the MDL is more narrow than the role  
21 you've served in other cases.

22 What topics have you opined  
23 about in other cases that you are not  
24 intending to opine about in the MDL?

25 A. So I am not doing general

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1 causation in the MDL, although I am indeed  
2 providing opinions on certain aspects of the  
3 cause and effect relationship such as -- you  
4 know, I talk about biologic plausibility,  
5 underlying knowledge about different  
6 toxicities of the compounds over time, but  
7 I'm not doing a full causation analysis in my  
8 MDL report, and hopefully you see that when  
9 you read the report.

10 Q. So as you sit here today,  
11 Dr. Plunkett, you are not intending to offer  
12 the opinion in the MDL that Johnson's baby  
13 powder causes ovarian cancer; is that  
14 correct?

15 A. Not in those words. I think if  
16 you read my report, I talk about the  
17 fact that Johnson -- it's my opinion that  
18 Johnson's baby powder increases the risk of  
19 cancer -- ovarian cancer, which is a  
20 different assessment than the way you stated  
21 it.

22 Q. All right. And it is -- as you  
23 sit here today, Dr. Plunkett, it is your  
24 understanding that you are not being offered  
25 to give a, as you termed it, a general

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1 causation opinion in the MDL, correct?

2 A. That's my understanding, yes.

3 Q. Now, you mentioned that the  
4 analysis as to whether a substance increases  
5 the risk of a particular outcome is different  
6 than a causation analysis.

7 Can you explain to me what you  
8 meant by that?

9 A. So I discussed this yesterday  
10 in my deposition. There's -- there's a  
11 process called risk assessment. Sometime --  
12 in the area of consumer products you can also  
13 refer to it as safety assessment. And then  
14 there's the process of what I call general  
15 causation analysis, or full causation  
16 analysis.

17 So even though the types of  
18 information that are considered may overlap  
19 between those two, the outcome or the  
20 statements or the -- the way you go about  
21 assessing the information is a bit different.

22 Q. Explain to me how they're  
23 different.

24 A. So in a risk assessment, the  
25 process starts with setting out some basic

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1 principles of, first, is there a hazard, is  
2 the first step. Is there a hazard that would  
3 be relevant to human health.

4                   Then looking at the data and  
5 determining whether that -- that body of data  
6 allows you to either quantify risk in some  
7 way or to qualitatively shows you that  
8 there's a change in risk based on exposure to  
9 the product.

10                  So your statement may be as  
11 simple as there's an increased risk, or you  
12 can take data in a risk assessment and do a  
13 quantification such as in a -- a cancer risk  
14 assessment based on an animal data set. You  
15 might actually calculate a cancer potency  
16 factor, for example. Those kinds of things.  
17 That's another application of risk  
18 assessment. Same basic process but focusing  
19 just, for example, on one study.

20                  My human health risk assessment  
21 or safety assessment, like the causation  
22 analysis, does look across all kinds of data,  
23 but my goal was not to analyze the data under  
24 the Hill considerations, which is what I  
25 would typically do, in order to go through

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1 the process of making that final opinion that  
2 indeed baby powder -- exposure to baby powder  
3 through genital application is a cause of  
4 ovarian cancer in women. That's -- to me,  
5 that's a different way to go about thinking  
6 about the question that you have to answer.

7 And also the -- some of the  
8 data that you evaluate is evaluated a bit  
9 differently. So, for example, in my  
10 increase -- in my issue of increased risk, I  
11 use the epidemiology as supporting evidence,  
12 but I'm really focused on -- on -- more on  
13 the underlying sort of the biologic  
14 information that we have that identifies  
15 hazard and risk. So looking at the animal  
16 data, the exposure potential for the product,  
17 and then using that along with what we know  
18 with the human experience to characterize  
19 risk.

20 Q. Is there a different level of  
21 certainty required to render a causation  
22 opinion than to render an opinion that  
23 there's an increased risk?

24 A. I don't know that I'd describe  
25 it quite that way but -- because to me it's a

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1 different process. I certainly have to be  
2 just as certain about what I say about risk  
3 when I do a risk assessment as I do about --  
4 as I do when I'm doing a causation analysis.

5 I don't -- maybe you mean  
6 something else, so maybe you can -- I mean,  
7 I -- I certainly use the same basic standards  
8 in my mind, how I weigh evidence to do the  
9 different processes, but I go about them in a  
10 little bit different way when I do a risk  
11 assessment versus -- versus a causation  
12 analysis.

13 Q. In your view, does the strength  
14 of the evidence have to be greater in order  
15 to determine that an agent causes a disease,  
16 for example, than it does simply to say that  
17 an agent increases the risk of a particular  
18 outcome?

19 MR. MEADOWS: Objection.

20 THE WITNESS: I don't think  
21 I've ever thought about it that way.  
22 I would say to you that strength --  
23 the strength of the association is a  
24 consideration under Hill that you  
25 apply the epidemiology data mainly, so

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1           that is a different consideration  
2           under causation than you do -- as you  
3           would do it in a risk assessment.

4           But the strength of the  
5           evidence, it's still a judgment based  
6           on your experience and training as far  
7           as whether or not there is enough  
8           information to be able to say that you  
9           believe that there is -- enough  
10          information to say that the risk is  
11          increased based on that exposure and  
12          those conditions and whatever the  
13          toxicity profile of that compound is.

14        QUESTIONS BY MS. BRANSCOME:

15        Q.        Okay. We'll get into this more  
16        a little bit later, but when you say that a  
17        risk is increased, is there a threshold level  
18        of increase that you need to see in order to  
19        render an opinion in a court of law that an  
20        agent increases the risk of a particular  
21        outcome?

22                   MR. MEADOWS: Objection.

23                   THE WITNESS: So I need you to  
24                  define what you mean by threshold.  
25                  Are you asking me a specific

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1           statistical test you would apply, or  
2           what are you asking?

3    QUESTIONS BY MS. BRANSCOME:

4           Q.       So understanding that for the  
5   most part if you're looking at statistical  
6   significance, you're looking whether the  
7   confidence interval crosses 1.

8                   Are you following?

9           A.       Yes, I know that, yeah.

10          Q.       All right. And so when you're  
11   evaluating, though, whether a particular  
12   substance, in this case Johnson's baby  
13   powder, increases the risk of an outcome,  
14   again, in this case ovarian cancer, would it  
15   be sufficient for you if that increase was  
16   .01 percent, for example?

17                   MR. MEADOWS: Objection.

18                   THE WITNESS: That doesn't make  
19   sense to me, an increase of .01  
20   percent, but maybe I can answer it  
21   this way for you based on what you've  
22   laid out there.

23                   Certainly when I do a risk  
24   assessment and I make it -- if I'm  
25   going to make the conclusion that I

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1 believe that it's my opinion to a  
2 reasonable degree of scientific  
3 certainty that exposure to baby powder  
4 in women increases the risk of cancer,  
5 I'm having to rely on -- I do rely on  
6 data that allows me to draw  
7 conclusions because either there's a  
8 statistical significant finding found  
9 or the -- there's a consistency among  
10 the pattern of the data that shows  
11 there's information that fits together  
12 consistently. And maybe -- you want  
13 me to explain what I mean by that?  
14 No?

15 Whereas I think what you're  
16 asking is when an epidemiologist  
17 applies -- looks at a body of -- in a  
18 causation analysis looks at a body --  
19 and I do this, too -- looks at a body  
20 of epidemiological studies and you  
21 weight the studies, obviously you're  
22 weighting the studies differently  
23 based on whether they have shown  
24 statistical significance or not,  
25 right?

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1                   And it isn't that it's a one to  
2                   one. If you have one positive and one  
3                   negative, that isn't how you may  
4                   decide to finally weight that  
5                   evidence, but certainly you have to  
6                   consider whether or not what was seen  
7                   or reported is showing you something  
8                   reliable -- or you can make a  
9                   statement reliably about whether or  
10                  not that finding was biologically  
11                  significant. And biologically  
12                  significant would typically be linked  
13                  to a finding that has statistical  
14                  significance in an epi study unless  
15                  the study was not designed to be able  
16                  to answer the question properly.

17                  So -- and I've discussed that a  
18                  little bit yesterday with Mr. Smith on  
19                  the issue of power to detect. So  
20                  that's something you do consider in  
21                  epi.

22                  But, yes, statistical  
23                  significance certainly goes into your  
24                  weight of the evidence there.

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.        Okay. You talked about you're  
3       intending to offer an opinion with respect to  
4       what a company is required to do under the  
5       regulations; is that correct?

6           A.        Yes.

7           Q.        Okay. What regulations are you  
8       specifically referring to?

9           A.        So cosmetic regulations that  
10      exist within -- so it's the entire process as  
11      I describe how cosmetic -- what -- are  
12      cosmetics subject to regulation by FDA? Yes.  
13      What are the types of things that companies  
14      have to do before they're marketed, what does  
15      the company have to do once the product is on  
16      the market, those kinds of things.

17          Q.        Have you ever worked directly  
18      for any regulatory agency?

19          A.        No, I have not.

20          Q.        And suffice it to say you have  
21      never been in a decision-making position  
22      within a regulatory agency, correct?

23          A.        That's correct, I have not.

24          Q.        Have you ever been in a  
25      decision-making position with respect to a

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1 company evaluating compliance with FDA  
2 regulations with respect to cosmetics?

3 A. Yes.

4 Q. Okay. What is your experience  
5 with respect to that?

6 A. So that's -- one of the clients  
7 that I currently work for where I am asked to  
8 provide input on advertising, promotion and  
9 labeling of some of the products and then  
10 also some of the ingredients that are being  
11 promoted for use to -- to produce cosmetic  
12 products. So it's the idea of providing that  
13 advice over my understanding of the  
14 regulations what can be said and can't be  
15 said about certain ingredients.

16 This company is involved in  
17 making both ingredients but also some  
18 finished products now based on -- it's a  
19 large company that owns a lot of little  
20 subsidiaries.

21 Q. My question, though,  
22 Dr. Plunkett, was, have you ever been in a  
23 decision-making position for a company  
24 evaluating compliance with FDA regulations  
25 with respect to cosmetics?

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1                   MS. PARFITT: Objection. Asked  
2                   and answered.

3                   THE WITNESS: So that's what  
4                   I'm saying. They're relying on my  
5                   input to make a decision on what will  
6                   go in the materials.

7                   QUESTIONS BY MS. BRANSCOME:

8                   Q.         Do you have decision-making  
9                   authority within that company or, as you  
10                  described it, are you providing advice and  
11                  input?

12                  A.         I'm providing advice, but the  
13                  things I'm advising on are the things that  
14                  happened. So in other words, they don't have  
15                  anybody in the company that understands the  
16                  process of what they can say. So I -- I  
17                  advise them that you need to remove this  
18                  language or that this is more appropriate  
19                  language. They make those changes, and then  
20                  that is what is done.

21                  So I agree, I'm not an employee  
22                  of that company. I am a consultant working  
23                  with the company, but it is a little  
24                  different than some of the work that I do  
25                  where I -- what I -- the advice that I'm

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1 giving is actually something that I know  
2 actually happened. Sometimes you give advice  
3 to companies, but it doesn't -- we have no  
4 idea whether the company actually follows our  
5 advice.

6 Q. My question is slightly  
7 different, Dr. Plunkett.

8 If you were to give advice to  
9 the company that you've referenced as having  
10 experience with cosmetic regulation  
11 compliance that that company chose not to  
12 follow, that company has the ability to  
13 ignore your advice, correct?

14 A. Yes, I would imagine that they  
15 could do that.

16 Q. Okay. Have you ever drafted  
17 regulations that relate to cosmetics?

18 A. Actually drafted a regulation?  
19 No, I have not.

20 Q. All right. You reference in  
21 your report language out of 21 CFR 740.1, and  
22 specifically -- you reference it in a few  
23 places. And I can direct you specifically to  
24 paragraph 22 in Exhibit 4.

25 A. Yes. I'm there.

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1 Q. All right. And do you see here  
2 you have replicated language from 21 CFR  
3 740.1 that reads, "The label of a cosmetic  
4 product shall bear a warning statement  
5 whenever necessary or appropriate to prevent  
6 a health hazard that may be associated with  
7 the product"?

8 Do you see that?

9 A. Yes.

10 Q. And you added emphasis on  
11 particular portions of this sentence,  
12 correct?

13 A. Yes, I did that, exactly.

14 Q. All right. Now there's a  
15 clause in this sentence that states,  
16 "Whenever necessary or appropriate."

17 Do you see that?

18 A. Yes.

19 Q. You did not emphasize that  
20 language; is that correct?

21 A. That's correct, I did not.

22 Q. What is your understanding  
23 as -- what you describe as an FDA regulatory  
24 specialist of the meaning of "whenever  
25 necessary or appropriate" in 21 CFR 740.1?

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1                   A.         So it's -- first off, you would  
2       use the common English language definition.  
3       I don't believe that those -- I haven't seen  
4       a definition separate within the regulations.  
5       Sometimes there will be.

6                   So based on that and my  
7       experience and the looking into what others  
8       have described about this, this is the idea  
9       of considering how the product is used, is  
10      one of the -- one of the concerns that you  
11      have, and whether or not the -- based on how  
12      the product is used and how the product is  
13      being sold, that in order to prevent a health  
14      hazard, a warning hazard -- a warning  
15      statement would be needed.

16                  Q.         Can you cite to me any language  
17       within the regulation or even supporting  
18       documentation, a comment, something of that  
19       nature, that would define "whenever necessary  
20       or appropriate" with respect to how the  
21       product is used?

22                  MS. PARFITT: Objection.

23                  THE WITNESS: I don't think I  
24       understand your question.

25                  Are you asking me to cite to a

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1 reference or a part of the regulation  
2 where they explain it, or what are you  
3 asking me? Guidance document or --

4 QUESTIONS BY MS. BRANSCOME:

5 Q. Yes. Can you point me to  
6 anything other than your personal view of the  
7 interpretation of this language that would  
8 tie the requirement "whenever necessary or  
9 appropriate" to how a product is used?

10 MS. PARFITT: Objection. Form.

11 THE WITNESS: I'll have to go  
12 look for you whether there's a  
13 guidance that states it that way.  
14 This is based on my experience in  
15 dealing with the products in the past.

16 I think that's also consistent  
17 with what is described, I would say to  
18 you, within -- it's consistent -- what  
19 I'm describing to you, it's consistent  
20 as well with how the CIR standard for  
21 safety assessment is done, looking at  
22 the issue of the -- of the -- of the  
23 use.

24 QUESTIONS BY MS. BRANSCOME:

25 Q. When you say that you're basing

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1 your interpretation of the clause "whenever  
2 necessary or appropriate" on your personal  
3 experience, can you point me to something  
4 specific?

5 MS. PARFITT: Objection.

6 THE WITNESS: Are you asking  
7 me -- are you asking me if I've ever  
8 had a company that I worked for that  
9 that particular clause in here was  
10 extremely important to how we  
11 interpreted it? I don't think I can  
12 point you to that. I don't recall  
13 ever having to do that specifically.

14 Or is it something different  
15 you're asking me?

16 QUESTIONS BY MS. BRANSCOME:

17 Q. Dr. Plunkett, I asked you what  
18 your basis was for interpreting the language  
19 "whenever necessary or appropriate" means  
20 that it's related to how a product is being  
21 used, and the answer that you provided was  
22 that it was based off of your personal  
23 experience.

24 So I'm asking you, what is that  
25 personal experience that gives you the basis

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1 for that specific interpretation?

2 MR. MEADOWS: Objection.

3 MS. PARFITT: Objection.

4 THE WITNESS: So it's in my  
5 experience in dealing with companies  
6 that make products and what types of  
7 warnings are put or not put onto -- or  
8 not -- or on labeling. So I don't  
9 know how else to answer it other than  
10 that.

11 I can go back and look at the  
12 guidance documents to see if that is  
13 described in another way, but I don't  
14 recall that.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. So as you sit here today,  
17 you're not able to provide me either with a  
18 third-party document or an independent  
19 document interpreting "whenever necessary or  
20 appropriate" as you've suggested today, nor  
21 can you give me specific example from your  
22 personal experience; is that correct?

23 MS. PARFITT: Objection.

24 THE WITNESS: Well, I  
25 certainly -- I'd have to go back and

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1           look at my documents in order -- the  
2           first part of your question, I'd have  
3           to go back and look. Off the top of  
4           my head, I can't tell what I would  
5           point you to.

6                 On the second one, I think I  
7                 was telling you, is I don't -- I've  
8                 never -- I don't have a client that  
9                 I've worked for where that part of the  
10               language was the only issue that I had  
11               to deal with when I'm looking at  
12               whether or not the product needs a  
13               warning or not.

14               So typically -- I'm just  
15               telling you that when I have looked at  
16               labeling for products and looked at  
17               the issue of does it need a warning  
18               statement, when I'm reading it as  
19               "whenever necessary or appropriate,"  
20               I'm looking at whether or not the  
21               ingredient that I'm concerned about  
22               within the product, how that is used  
23               or what the exposure pattern would be,  
24               route of exposure, how those things  
25               might relate to how I would assess the

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1                   safety issue at hand. And so that's  
2                   what I'm trying to tell you.

3       QUESTIONS BY MS. BRANSCOME:

4                   Q.        Okay. You also have --  
5                   changing topics a little bit, in this -- in  
6                   your report marked as Exhibit 4, if you could  
7                   turn to paragraph 10.

8                   On page 7, you state on the  
9                   first paragraph on page 7, "In other  
10                  instances I have directed others to perform  
11                  searches on my behalf," and this is with  
12                  respect to identifying documents for review  
13                  in forming your opinions.

14                  What did you mean by that?

15                  A.        So in addition to doing my own  
16                  searches of the database, sometimes I -- I  
17                  have called the attorney's office and asked  
18                  them to -- to do a search for certain things  
19                  that I'm looking for to add to. So in other  
20                  words, I have a document I've identified.  
21                  I'm looking for other documents like that in  
22                  the large millions and millions of documents  
23                  that are available. And so sometimes I will  
24                  ask attorneys to do -- to look in the  
25                  database for other documents like the ones

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1 that I've identified.

2 Q. And without getting into  
3 anything that would be -- that would call for  
4 information protected by the attorney/client  
5 privilege or attorney work product, what  
6 percentage of the overall searches for  
7 relevant documents from these particular  
8 databases that are discussed in paragraph 10  
9 would you say that you have done yourself as  
10 opposed to directed others to do?

11 A. Well, initially when I first  
12 started searching, those were my own searches  
13 exclusively. I would say that more recently,  
14 in the last year, since I haven't added any  
15 real new areas but there's new documents that  
16 have become available, so anything -- any of  
17 the searches probably in the last year that  
18 dealt with new discovery that was produced, I  
19 would have asked the attorneys to do some of  
20 the searching in that for me. Like I'm  
21 looking for documents that are similar to  
22 this document that I cited in my original  
23 report around this same frame that may be  
24 discussing this same topic area.

25 So in the last year I have

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1 asked them to do that more than I have done  
2 it, but initially it was what I did  
3 initially.

4 Q. Okay. Do you keep any records  
5 of the various document searches either that  
6 you have performed or you have asked to be  
7 performed?

8 A. No, I don't. My record would  
9 be -- the initial -- the record would have  
10 been what I listed in my reliance list for  
11 you in the initial report, but since then it  
12 would just be what is going to be changing  
13 within my reliance list, looking at  
14 additional documents. That's the only way I  
15 could identify for you. That would be my --  
16 my trail to know what was new and what was  
17 not.

18 Q. My question is slightly  
19 different. Understanding that you have  
20 provided to some extent a record of the  
21 documents, my question is: Do you have any  
22 type of record for the nature of the  
23 searches, what it was that you set out to  
24 identify in the database and how did you go  
25 about finding those documents?

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1                   A.         So that might cross over into  
2 work product because it's not my database,  
3 but I don't know how to answer that. I mean,  
4 I'm sure -- it's very possible that in the  
5 database you can track that, but I -- I don't  
6 know.

7                   MR. MEADOWS: Okay.

8                   THE WITNESS: I don't have  
9 anything saved on my computer that  
10 way, but when you go to the database  
11 itself, it's possible you could track  
12 that. I just don't have a record on  
13 my computer in my office.

14 QUESTIONS BY MS. BRANSCOME:

15                  Q.         When you made the decision at  
16 some point in time -- it may have been even  
17 prior to you issuing your first report --  
18 that you wanted to look at company documents,  
19 did you set out specific categories of  
20 documents that you wanted to review?

21                  A.         Not so much categories but key  
22 words. So -- and areas. I guess areas is  
23 what I -- yes, I was focusing, for example,  
24 in my initial report on documents that  
25 described what was known -- what the company

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1 was discussing about cancer, ovarian cancer,  
2 cancer generally. So that was a key word  
3 used.

4                   And then I also was linking  
5 that in different searches with different  
6 time periods such as the NTP review process  
7 and dates. You can, you know, narrow down by  
8 dates or by the CIR process. Those kinds of  
9 things.

10                  So I did start with that,  
11 trying to understand what -- what is -- what  
12 was in the company files or in the files I  
13 had access to, the database, that dealt with  
14 those kinds of things because those aren't  
15 things that I could get to publicly.

16 Obviously in the literature. So I had to --  
17 if I wanted to understand what the company  
18 knew, I had to go into their database to find  
19 out, you know, what they knew -- what they  
20 knew or were discussing over time about the  
21 ovarian cancer issue or about asbestos in  
22 talc or about CIR process, things like that.

23                  Q.       Using the reports that you have  
24 produced, Exhibits 2, 3 and 4, really, and  
25 the full -- the entirety of the materials

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1 that you have produced in the MDL, is there  
2 any way that someone reviewing those  
3 documents, and those documents alone, could  
4 replicate the searches that you have  
5 conducted in the company databases?

6 MR. MEADOWS: Objection.

7 THE WITNESS: I don't know.

8 That's a good question. I've never  
9 thought about whether you could  
10 replicate or not.

11 I mean, I think I've told you  
12 what I did. My strategy was to focus  
13 on topic areas. So I think you  
14 might -- by topic areas, if you use  
15 the same kinds of topics areas as  
16 described, I think you would come up  
17 with documents that -- what it focused  
18 down to.

19 For example, I also would  
20 sometimes, as linking those words, I  
21 might put in J&J documents only or  
22 Imerys documents only, because the  
23 database has a variety -- and the  
24 PCPC. There's some different ways by  
25 the Bates numbers that you can

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1           segregate documents as well. But I  
2           don't know other than that. That's  
3           all I can tell you.

4       QUESTIONS BY MS. BRANSCOME:

5           Q.       You would agree with me that  
6       your report does not contain a complete  
7       explanation of the process by which you  
8       identify company documents to review,  
9       correct?

10          A.       I haven't laid out my search  
11       structure, that is true.

12          Q.       All right. Now, the articles  
13       that you have listed on your reliance list,  
14       have you read each and every one of those  
15       articles?

16          A.       Unfortunately, yes, over time I  
17       have. Some of them I have only read parts of  
18       them. For example, if I started reading a  
19       document and I felt that it was something I  
20       pulled that really wasn't directly on point  
21       for an area I'm covering, I may not have read  
22       every word, but certainly I have been through  
23       each of those, yes.

24          Q.       Are there any articles in your  
25       reliance list, that you maintained on your

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1 reliance list, that you read, but then once  
2 you started reading decided weren't relevant  
3 to the opinions that you were offering?

4 A. I would have to look to answer  
5 that for you. I don't know. If you want me  
6 to do that, I'd have to look.

7 Q. I ask you more as a process  
8 matter.

9 A. Oh.

10 Q. If you pull an article and you  
11 start reading it and you realize that it is  
12 not relevant to the opinions that you offered  
13 in this case, the example that you just gave,  
14 is it something that you would include in  
15 your reliance list?

16 A. Yes, I -- I have given you  
17 everything I retrieved. So if I retrieved  
18 it, you would have, yes, absolutely.

19 Q. Okay. So it's fair to say of  
20 the articles that are on your reliance list,  
21 you could not say as you sit here today that  
22 you have read each and every word of each and  
23 every one of them, correct?

24 A. That's correct. And I could  
25 probably tell you -- I could give you a

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1      little guidance in that possibly if I went to  
2      my list, I could try to pull some out that I  
3      recognize, but that's all I would be able to  
4      do for you.

5            Q.        Okay.    How did you go about  
6      identifying what articles you wanted to  
7      review in forming your opinions in the MDL?

8            A.        So first off, I went back to  
9      what I already had.   So my MDL report is a --  
10     is a compilation of a lot of material that's  
11     in my first few reports.   That was the basis  
12     for some of the things that went into it.

13                  So I didn't -- I did do,  
14      though, a updating on literature searches for  
15      the MDL report, looking for anything new, for  
16      example, in the area, especially the area of  
17      cancer data or reports of dealing with  
18      ovarian cancer either -- or any articles  
19      dealing with the link between inflammation  
20      and cancer, ovarian cancer, generally.

21      That's one of the areas I updated looking at.

22                  And then I did -- I don't think  
23      I did any large, new searches, however,  
24      because honestly the areas covered here are a  
25      little narrower than what was covered here.

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1 I don't believe that there was any from the  
2 published -- the publicly available medical  
3 literature. There wasn't a need to do a  
4 whole new area of search. It was more  
5 updating the things that I've done in the  
6 past.

7 So it's a real easy search to  
8 update because you can just put in talc and  
9 cancer and just look at -- get lots, but you  
10 can then just start chronologically and look  
11 what was published in the last year, for  
12 example.

13 Q. Okay. Earlier when we were  
14 discussing the fact that you in some  
15 instances have asked your husband to pull  
16 articles, have you maintained any records of  
17 the searches that you have done with respect  
18 to scientific literature, including the  
19 searches that you have asked your husband to  
20 do?

21 A. I have not. It's possible that  
22 there are records on billing from the library  
23 that tells you how many I ordered at  
24 different times, but that is the only  
25 records, because we do have to pay the

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1 library for the retrieval.

2 Q. Okay. And if I understood what  
3 you said earlier correctly, you indicated  
4 that any article you have ever pulled for  
5 review, you have listed on your reliance  
6 list; is that correct?

7 A. Yes. And when I -- and let's  
8 just make sure we're talking about the same  
9 thing.

10 So, you know, in my reports I  
11 typically have articles cited in the report  
12 separate from the reliance list. So I'm  
13 talking about the reliance list, right?  
14 Okay.

15 So -- because I do -- I do  
16 usually -- I don't know whether I did that in  
17 this report, but I typically have a list of  
18 articles cited at the back called references,  
19 that is, things that you're actually seeing  
20 in the report body, and then there should be  
21 a separate reliance list sent to you as an  
22 appendix. I don't know what the appendix  
23 was.

24 Q. Well, so then let's clarify  
25 that. So, Dr. Plunkett, when you're

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1 referring to the reliance list, are you  
2 referring to the list of articles that begins  
3 on page 40 of Exhibit 4, or is there a  
4 separate document?

5 A. There's a separate document.

6 So it -- that's -- I usually call reliance  
7 list the separate document. I call this  
8 references cited. So I apologize for that  
9 confusion.

10 So these, I have read every  
11 word. If it's in my reference list, those  
12 are not an issue of not having read every  
13 word, and these should all be cited somewhere  
14 in the report.

15 Q. Okay. If you could turn to  
16 paragraph 21 in your initial report.

17 A. Yes, I'm there.

18 Q. Okay. So we're looking at  
19 paragraph 21 in Exhibit 2. This is on  
20 page 10.

21 Do you see there is a sentence  
22 here that refers to -- it's referring  
23 generally to the topic of the ability of talc  
24 to migrate from the site of application to  
25 the ovaries.

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1                   Do you see that?

2                   A.       Yes.

3                   Q.       And then the next sentence  
4       states, "This issue was discussed by  
5       scientific and regulatory bodies that review  
6       the toxicokinetics of talc."

7                   Do you see that?

8                   A.       Yes.

9                   Q.       And in parentheses it  
10      identified EPA 1992, IARC 2010, and CIR 2013.

11                  Do you see that?

12                  A.       Yes.

13                  Q.       Okay. And then if you could  
14      turn to Exhibit 4, which is your MDL report,  
15      at paragraph 43. It's on page 28.

16                  Are you with me?

17                  A.       Yes, I am.

18                  Q.       You see that the exact same  
19      sentence appears -- well, not the exact same.  
20      It's been slightly modified to combine the  
21      first two sentences. But here you cite only  
22      to EPA 1992 and IARC 2010.

23                  Why did you remove CIR 2013?

24                  A.       Because of my further  
25      evaluation since my initial report in 2016 of

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1 the process that was involved in the drafting  
2 of the CIR and the actual production of the  
3 report.

4 Q. Is it your position that the  
5 migration of talc was not evaluated as part  
6 of CIR 2013?

7 A. No. That's not my position,  
8 no.

9 Q. Okay. And so would the  
10 sentence that's contained in paragraph 43 in  
11 Exhibit 4, which is your MDL report, if you  
12 cited to CIR 2013 in the parenthetical there,  
13 would that not be an accurate citation?

14 A. I believe it would not be an  
15 accurate citation because I have formed  
16 opinions about the reliability of that  
17 document at this point in time.

18 So it has to do with -- I'm  
19 citing to authorities here that I believe are  
20 reliable as far as the discussion that I see,  
21 and it's a different -- I have a different  
22 opinion now about the CIR report, which I lay  
23 out in pretty detail, I think.

24 In fact, if you go to my  
25 section following this now in -- you'll

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1 understand one of the issues I had was the --  
2 the difference in the evidence that was  
3 actually available once you dig into it a  
4 little further versus what they actually  
5 reviewed. That's one of the issues.

6 Q. And I'll follow up with some  
7 more questions about the CIR, but my question  
8 here is, the sentence in your report simply  
9 states, "The migration of talc internally  
10 after perineal application was discussed by  
11 scientific and regulatory bodies that review  
12 the toxicokinetics of talc."

13 Would it be inaccurate to say  
14 that as part of the CIR 2013 process that  
15 body did, in fact, discuss the migration of  
16 talc internally after perineal application?

17 A. It is true that they did  
18 discuss it. I just have an issue with the  
19 reliability of their findings.

20 Q. And so you made the decision to  
21 just remove it from the citation; is that  
22 correct?

23 A. Yes, at this point -- at this  
24 point, at this report, that's exactly right.

25 Q. All right. And then I had

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1 another question. In paragraph 43, you added  
2 two studies from your prior -- that were --  
3 that did not appear in your prior report, and  
4 it was Gardner 1981 and Edelstam 1997. This  
5 related to animal studies showing that in  
6 some species talc can migrate from the lower  
7 to the upper genital tract?

8 A. Yes.

9 Q. Okay. Were those studies that  
10 you were aware of before drafting your prior  
11 reports?

12 A. I don't know that they -- I  
13 can't answer that without looking at my  
14 reliance materials for the original report.  
15 I did identify additional articles, and  
16 there's also additional articles cited here  
17 in earlier paragraph 43 that were not cited  
18 in my original report as well. I don't think  
19 I had the -- the Kunz article then cited.  
20 I'd have to go back and look.

21 So it's possible that they were  
22 in my -- when I say my reliance materials, my  
23 original report also had a larger list of  
24 literature I didn't cite. So I'd have to  
25 look. I can't tell you whether I had them or

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1 I did not.

2 Q. Okay. With respect to Edelstam  
3 1997 study, do you happen to know the title  
4 of that article? Even an approximation would  
5 work.

6 A. It'll be -- should be back  
7 here. Just a second. If it's not here,  
8 that's a mistake.

9 Oh, here it is. "Retrograde  
10 migration of starch in the genital tract of  
11 rabbits."

12 Q. So you are citing that article  
13 for the proposition that animal studies have  
14 demonstrated that talc can migrate from the  
15 lower to upper genital tract?

16 A. Yes, I'm citing it because it's  
17 relevant to the issue of particle migration,  
18 which talc is a particle. So, yes, that's  
19 correct.

20 Q. Okay. But that study did not  
21 specifically deal with talc migration,  
22 correct?

23 A. No. Well, it -- it's relevant  
24 to talc migration, but you're exactly right,  
25 they looked at the starch migration, yes. Or

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1 particles that were starch, yes.

2 Q. We'll cover this in more  
3 detail, but is it your opinion that all  
4 particles have similar characteristics with  
5 respect to their ability to migrate in the  
6 genital tract?

7 A. It's my -- I don't know if I'd  
8 state it quite that way. What I would say is  
9 that the evidence shows that particles  
10 generally have the ability to move up the  
11 reproductive tract in women, yes, and that if  
12 a particle is one that is similar to talc or  
13 some of the other ones where the information  
14 has been collected, I would characterize that  
15 as being within that, quote/unquote,  
16 relevance of particles.

17 That doesn't mean all  
18 particles, but certainly in the ones that I  
19 have looked at and the data I've relied upon,  
20 there's a variety of different types of  
21 particles or substances that have been  
22 studied and shown to be able to migrate.

23 Q. So let's take Edelstam 1997 as  
24 an example.

25 Did you do any analysis that

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1 you can point me to that establishes that  
2 starch would have a similar migration pattern  
3 as talc?

4 A. So I would say that the paper  
5 itself shows -- talks about the movement of  
6 starch, but are you asking something  
7 different?

8 Are you asking me have I done a  
9 specific analysis of any differences that may  
10 occur between the migration pattern of starch  
11 and talc? Is that what you're asking me?

12 Q. That is what I'm asking you.

13 A. I certainly didn't do an  
14 in-depth analysis of the differences, no, but  
15 based upon my review of the literature, I  
16 believe that that paper is relevant to the  
17 overall question of migration of particulate  
18 through the reproductive tract, including  
19 particles of talc.

20 Q. Regardless of whether or not it  
21 was an in-depth analysis, can you point me to  
22 anything other than just your belief after  
23 having read these articles that starch and  
24 talc would have similar migratory  
25 characteristics in the human or animal

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1 genital tract?

2 MS. PARFITT: Objection.

3 THE WITNESS: Again, I haven't  
4 done an in-depth analysis. I mean, as  
5 a toxicologist, there are differences  
6 between starch and talc, absolutely.  
7 For example, starch would -- I would  
8 expect to be more easily solubilized  
9 within fluids, and so that could  
10 affect the ability of them to actually  
11 not migrate as well as a talc  
12 particle, which would be less soluble  
13 than the starch would be.

14 And there's -- I even --  
15 there's a paper I have in here, and I  
16 can look for it if you want, that  
17 talks about that difference, and it's  
18 one of the issues of cornstarch versus  
19 talc, on whether or not you would  
20 expect to get the long-term chronic  
21 responses with the difference between  
22 those two substances.

23 So I do think there's  
24 difference, absolutely, as  
25 toxicologists generally. And the only

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1 reason I'm citing this paper is  
2 because I'm trying to be complete  
3 about people that have looked at this  
4 issue. And certainly it was a study  
5 that looked at this issue and talks  
6 about the movement.

7 But I wouldn't expect starch  
8 and the talc to have the same  
9 liabilities, and I also wouldn't  
10 expect them to move exactly the same  
11 speed maybe. That's very true.

12 QUESTIONS BY MS. BRANSCOME:

13 Q. So you would agree with me that  
14 Edelstam is not a study demonstrating that  
15 talc can migrate from the lower to upper  
16 genital tract, correct?

17 MS. PARFITT: Objection. Form.

18 THE WITNESS: I wouldn't say it  
19 that way. What I would say instead is  
20 that Edelstam is a study that forms  
21 the overall weight of the evidence for  
22 the ethics -- for the studies that are  
23 available that address the issue of  
24 migration, but certainly it is not  
25 studying talc. So I don't disagree

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1                   with you there.

2                   Unfortunately, the majority of  
3                   the information that I have relied  
4                   upon, and others such as the FDA in  
5                   making their statements about  
6                   migration, is not all directed studies  
7                   just to talc. It's looking at the  
8                   issue of particle movement.

9                   QUESTIONS BY MS. BRANSCOME:

10                  Q.         Now, in terms of doing your  
11                  risk assessment -- well, let me get back. We  
12                  covered this earlier, and I want to return to  
13                  it for a moment. Just to confirm: For your  
14                  work in the MDL, you did not do a Bradford  
15                  Hill analysis, correct?

16                  A.         I did not sit down and do a  
17                  Bradford Hill analysis when I started writing  
18                  this report. I have done a Bradford Hill  
19                  analysis in the past, which is in my original  
20                  reports, but I certainly did not redo a  
21                  Bradford Hill when I sat down to draft my MDL  
22                  report, that is true.

23                  Q.         Okay. Let me be more precise.

24                           In the report that you have  
25                  produced that contains a description of your

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1      opinions in the MDL, you have not set forth a  
2      Bradford Hill analysis in that document which  
3      is identified as Exhibit 4, correct?

4                  A.        That is true, yes.

5                  MS. PARFITT: Objection.

6      QUESTIONS BY MS. BRANSCOME:

7                  Q.        And in fact, the paragraph that  
8      you -- or paragraphs that you have in your  
9      prior reports that reference a Bradford Hill  
10     analysis, those have not -- those have  
11     actually not been replicated in any form in  
12     Exhibit 4, correct?

13                A.        Yes, because, again, it was not  
14     my role to do general cause.

15                Q.        Okay. So then when we look at  
16     the methodology that you employed in reaching  
17     your opinions that are contained here in  
18     Exhibit 4, how would you characterize the  
19     methodology?

20                A.        As I have in the report. I  
21     talk about it being a risk assessment or a  
22     safety assessment, that you could use those  
23     terms interchangeably here. And then I've  
24     also used a weight of the evidence as a tool  
25     to go through the different steps of the risk

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1 assessment.

2 Q. Okay. What publication would  
3 you direct me to that has used the same  
4 methodology that you have used to reach your  
5 opinions in Exhibit 4?

6 A. I think I cite you to -- cite  
7 you to some of those. You could -- well, the  
8 directly relevant one would be looking at the  
9 chapter on risk -- toxicology in the  
10 reference manual on scientific evidence.

11 You can also go to the NRC  
12 report where they -- it lays out the  
13 different steps that you use when you kind of  
14 break data apart into exposure versus  
15 response information.

16 And then I cite to -- there are  
17 some guidance documents that I cite to, and  
18 this is in paragraph 13. And I'd have to  
19 pull them out again to tell you which ones  
20 relate to different pieces because some of  
21 these are -- some of these documents are  
22 specific to only, for example, maybe one part  
23 of what I did.

24 But certainly the risk  
25 assessment process at IARC is -- they do what

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1 I call a hazard assessment. They identify  
2 hazard and they couldn't quantify risk, but  
3 the steps they go through are essentially the  
4 same types of steps that I went through as  
5 far as gathering data on not just response  
6 but also the potential for exposure and how  
7 that relates to the response.

8 And then also the data that  
9 I've collected on the biologic effects of  
10 talc, toxicology of talc, are also discussed  
11 within that document as well.

12 Q. Okay. Focusing specifically on  
13 the weight of the evidence tool, as you  
14 describe it, is there a particular document  
15 or publication that I would go to that could  
16 lay out the same process that you used for  
17 how you weighted certain pieces of evidence?

18 A. So the documents that I've  
19 cited for you in paragraph 13 talk about what  
20 weight of the evidence is generally, but if  
21 you read what it is, it's essentially a  
22 process that each scientist brings their  
23 experience, training and judgment to.

24 So I try to lay out for you in  
25 my discussion of the literature my thought

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1 process as I review each piece of  
2 information, and that is what you do as part  
3 of weight of the evidence. You gather all of  
4 the relevant information that you can find  
5 that address the question you're trying to  
6 answer, and since I'm looking at both  
7 exposure and response, I gather different  
8 pools of information.

9 Q. You would agree that there are  
10 ways to do a weight of the evidence  
11 assessment of published literature that  
12 assign, for example, quantitative values to  
13 particular pieces of evidence, correct?

14 A. Certain individuals have put  
15 together, but there's no one general accepted  
16 process that everyone uses. So I -- that's  
17 the issue. Again, there are certain --  
18 certain cases where I've seen that done, and  
19 then there are many -- most cases that it's  
20 not what's done.

21 Q. Okay.

22 A. Another body, by the way, that  
23 I -- it's new. It's not in paragraph 13. I  
24 just want to make sure I tell you that so  
25 we're clear. If you look at the Canadian

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1 document, they also -- in fact, a lot of what  
2 they have, you'll see the same literature  
3 described within my assessment as well.

4 Q. So using the Canadian  
5 assessment as an example, for instance, in  
6 that assessment there were actually values  
7 assigned to particular pieces of literature,  
8 correct?

9 A. Mainly the epidemiological  
10 literature, that is true. Again, but I'm not  
11 doing causation, so I didn't approach it that  
12 way.

13 But certainly if you look at  
14 what I did, it's consistent with that because  
15 I talk about the differences between the  
16 limitations of a case-control versus a  
17 prospective study. I talk about both the  
18 positives and the negatives within the  
19 database, but I don't lay it out in a table  
20 like they do. But it's certainly the same  
21 basic process.

22 I was actually quite surprised  
23 at how similar the database of information  
24 that they reviewed was to what I honed in on  
25 as well.

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1                   Q.         Okay. As you were forming your  
2     opinions, Dr. Plunkett, about whether or not  
3     there is a risk associated with the use of  
4     Johnson's baby powder with respect to ovarian  
5     cancer, how do you keep track of the pieces  
6     of scientific evidence that you have reviewed  
7     and the respective weight that you give to  
8     them?

9                   Presumably you did not read  
10    everything in one day, for example?

11                  A.         No. That's correct. So I  
12    typically will -- I typically will save the  
13    papers -- when I read the papers, I will  
14    often highlight in yellow information that I  
15    think is going to -- will be extremely  
16    relevant. I don't put notes on the document.  
17    I highlight in yellow on the PDF file to use  
18    that to write.

19                  And I also start drafting  
20    report very early, which then gets  
21    overwritten and actually ends up looking like  
22    an outline that eventually becomes the  
23    report.

24                  So one of the ways I keep track  
25    of things is I may put a paragraph name that

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1 I know I'm going to write, such as exposure  
2 migration, and then I -- as I'm reading a  
3 paper, I'll type in a paper -- the ones that  
4 I believe are important to my overall  
5 assessment. So I will do that as I'm -- as  
6 I'm going through the evidence.

7 So that's one of the tools I  
8 use, but I don't keep notes. I just kind of  
9 use that as a living document that eventually  
10 becomes a report.

11 Q. Do your opinions ever change as  
12 you read additional pieces of scientific  
13 evidence?

14 A. Yes, it does. It may change.  
15 And it often -- often the changes, though,  
16 are not that I believe -- with the exception  
17 of epidemiology. In other areas.  
18 Epidemiology is a little bit different issue  
19 when you're reviewing studies.

20 But on toxicology I always  
21 start with reviews and regulatory  
22 authorities, looking at what others have said  
23 generally about the toxicology. And so even  
24 though I may refine opinions differently or I  
25 might change, I certainly wouldn't agree to

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1 work on a project to start with if my initial  
2 reviews on hazard, for example, didn't  
3 convince me that I believe that there is a  
4 hazard. But you refine it from there.  
5 That's exactly right.

6 So there are cases, however,  
7 where I'm asked to work on a project where  
8 there is no review or regulatory authority or  
9 any kind of assessment over a period of  
10 years, and in those cases there are times  
11 when I start working on a project and I stop  
12 and say, "I can't do this." Because that  
13 happens, yes.

14 So opinions do change sometimes  
15 based on review of additional information.

16 Q. Is there any documentation that  
17 you've produced either in your report or  
18 otherwise in the MDL that would allow someone  
19 reviewing the material to understand the  
20 order in which you reviewed materials or the  
21 specific weight that you assign them?

22 A. So order of review, no. I  
23 don't think you would know that other than --  
24 you will note order of review if you look at  
25 the differences in the literature cited in my

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1 original report versus in the MDL.

2 So in my original reliance  
3 list, if there were documents that weren't  
4 there and they're now here, obviously that  
5 tells you it was a review.

6 On the issue of a -- of the  
7 weight of the evidence process, the only  
8 answer I can give you for that is that  
9 articles that I believe are -- are reliable,  
10 are relevant and are -- those are kind of  
11 the -- you look at the reliability of the  
12 studies, whether they're peer-reviewed or not  
13 or if they have proper controls put into  
14 place, things like that, whether or not  
15 the -- they're relevant to the question at  
16 hand. That you can get from looking at how I  
17 discuss them in the document. But certainly  
18 there's no, like, summary of that.

19 But certainly -- I think you  
20 understand -- you should understand when you  
21 read my report what weight I'm giving based  
22 on how I'm describing those -- those  
23 materials. I mean, it's --

24 Q. Well, for example, you do have  
25 different studies that you've identified in

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1 your report that have been criticized by  
2 others at some point in time, correct?

3 A. Yes, that's true.

4 Q. Okay. Now, in some instances  
5 you state that you then give little weight to  
6 those studies, correct?

7 A. Yes.

8 Q. But in other instances you find  
9 the criticized study to be helpful and  
10 informative, correct?

11 A. That's true. Because, again,  
12 judgment -- as anybody does weight of the  
13 evidence, different scientists can have  
14 different judgment.

15 Mainly, I think, when I look at  
16 the differences in that -- in that regard, I  
17 think you should pay attention to what the  
18 person is. So as a toxicologist, I may view  
19 a certain type of -- piece of data very  
20 differently than an epidemiologist may view  
21 it, as far as the reliability or the  
22 relevance, because we're coming at it from a  
23 different training and experience and  
24 judgment -- set of judgment on what is  
25 important to a toxicologist when I'm talking

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1 about risk versus how an epidemiologist might  
2 talk about risk.

3 Q. Could two different  
4 toxicologists review the same piece of  
5 literature and give it very different weight?

6 A. I don't know about different  
7 weight, but they certainly -- I know people  
8 come to different conclusions based on their  
9 overall assessments. That happens,  
10 definitely. I mean, there are always going  
11 to be individuals that look at things  
12 differently.

13 I know in this case there are  
14 people -- I've seen defense experts that  
15 reports in -- not in the MDL but in other  
16 cases, where people disagree with some of my  
17 opinions, and I disagree with their opinions.  
18 That happens.

19 Q. Okay. And so if I were --  
20 well, let me just ask something. You have  
21 not provided any sort of quantitative  
22 assessment of the weight that you gave  
23 different pieces of evidence that you cite in  
24 forming your opinions in the MDL, correct?

25 MS. PARFITT: Objection.

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1 Misstates her testimony.

2 MR. MEADOWS: Objection.

3 THE WITNESS: So I don't report  
4 for you a table where I quantify that,  
5 that is correct, but certainly that  
6 is -- because, again, based upon  
7 looking at the way that I was trained  
8 and the documents that I'm talking --  
9 I'm pointing you to to describe how to  
10 do weight of the evidence, it is  
11 not -- it is not a numerical exercise,  
12 how many here, how many there, this  
13 one gets 5 points because of this or  
14 6 points because of this.

15 It's more an issue, again, of  
16 judgment. It's the idea of looking  
17 across all of the available  
18 information and determining whether or  
19 not, based on that, it's your opinion  
20 that there -- that, for example,  
21 talc -- talc's toxicity profile  
22 includes cancer. That's one of the  
23 judgments -- weight of the evidence  
24 judgments you make, for example.

25

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.       So -- but, Dr. Plunkett, just  
3       to be clear, you do not provide a numerical  
4       value to the particular pieces of evidence  
5       that you have considered as part of your  
6       weight of the evidence assessment in the MDL,  
7       correct?

8                   MS. PARFITT: Objection. Form.

9                   THE WITNESS: So I do not  
10          provide a numerical value as you see  
11          it laid out, for example, in the  
12          Canadian table, but certainly I do  
13          judge articles that I include in my  
14          weight of the evidence based on a  
15          system that includes different  
16          considerations such as -- like I said,  
17          peer-reviewed or not, that makes an  
18          issue.

19                  Whether or not the study that's  
20          being reported is the only one -- the  
21          first or is this something that is --  
22          that is describing an assessment  
23          that's been done by someone else and  
24          so you see a repetition or a  
25          consistency among the studies that

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1                   you're looking at.

2                   The robustness of the data.

3                   For example, the NTP GLP quality  
4                   animal study, very high quality in the  
5                   weight of the evidence. And I talked  
6                   to you about that. In fact, it --  
7                   even though people criticize that  
8                   study, that study is very valuable for  
9                   looking at biologic changes that are  
10                  consistent with a carcinogenic  
11                  mechanism being initiated.

12                  So even though you may say that  
13                  you can't quantify risk from that  
14                  animal study as far as calculating a  
15                  cancer potency factor, what you can do  
16                  is use that study of high quality to  
17                  make judgments within a weight of the  
18                  evidence for risk.

19                  QUESTIONS BY MS. BRANSCOME:

20                  Q.         Dr. Plunkett, you understand I  
21                  have seven hours today, and I -- while I'm  
22                  very interested in the answers that you give,  
23                  if we could just -- we will get to things  
24                  like NTP when we get there, if you could just  
25                  attempt to answer the question that I've

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1 asked.

2 I simply asked the question:

3 Are there numerical values assigned to the  
4 particular pieces of evidence that you have  
5 considered as part of your weight of the  
6 evidence assessment in reaching your opinions  
7 in the MDL; yes or no?

8 A. And I said to you, not in the  
9 way that it's done -- I assume you're  
10 referring to something like what was done --  
11 what's in the Canadian epidemiology table. I  
12 have not done that, no.

13 Q. Okay.

14 A. That's exactly right.

15 Q. Have you provided a qualitative  
16 chart, for example, of the evidence that you  
17 have considered in forming your opinions in  
18 the MDL?

19 MS. PARFITT: Objection. Form.

20 THE WITNESS: I don't know what  
21 you mean by qualitative chart. I  
22 certainly have -- I certainly, I  
23 believe, have given you qualitative  
24 descriptions of my weight within my  
25 discussions of each study, yes, I have

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1                   done that.

2       QUESTIONS BY MS. BRANSCOME:

3                   Q.         You mention in response to the  
4       prior question that you have a system for  
5       weighting the pieces of evidence that you  
6       have reviewed.

7                   Can you point me to paragraphs  
8       in your report marked Exhibit 4 that would  
9       outline in detail the system that you used to  
10      apply different weight analysis to different  
11      pieces of evidence?

12                  MS. PARFITT: Objection. Form.

13                  THE WITNESS: And I think I  
14       answered that, that there's no system  
15       written down by anyone. But what  
16       there is, instead, is if you read  
17       these -- if you read these  
18       descriptions of use of weight of the  
19       evidence that I've cited in  
20       paragraph 13 as well as the discussion  
21       of methodology in the Canadian  
22       document, that is consistent with what  
23       I do. It's the idea that you start  
24       with a literature search for  
25       peer-reviewed, publicly available

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1 information. You look at the quality  
2 of the studies, the statistically  
3 significant findings. Those are all  
4 things that are discussed within these  
5 documents I'm pointing you to.

6 QUESTIONS BY MS. BRANSCOME:

7 Q. Now, you --

8 A. But it's -- it's -- I don't  
9 know of anyone who has written down a  
10 specific system that applies in all  
11 circumstances, no.

12 Q. Okay. Have you written down a  
13 system that applies specifically in this  
14 case?

15 A. I think I have tried to do that  
16 for you when I describe what I did.

17 Q. Okay. You just referenced the  
18 fact that your system can be found in the  
19 Canadian document.

20 You agree that the Canadian  
21 analysis was actually published or produced  
22 after you had completed your report in the  
23 MDL, correct?

24 MS. PARFITT: Objection. Form.

25 THE WITNESS: Certainly it was

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1                   published afterwards, and what I  
2                   thought I said to you was that if you  
3                   look at that document -- it's not in  
4                   paragraph 13, but if you look at that  
5                   document, it lays out a process. And  
6                   I wouldn't call it a system. It's a  
7                   process. It's a process by which you  
8                   screen information for relevance to  
9                   the question being asked and how,  
10                  then, based on that, you look at  
11                  characteristics of that information  
12                  such as -- and I tried to give you  
13                  some of those.

14                  And I've said this before in  
15                  depositions in these cases. You know,  
16                  you look at the issue of whether or  
17                  not the study was peer-reviewed,  
18                  whether or not there was  
19                  statistically -- statistical  
20                  significance or at least statistics  
21                  applied to the data. What was the  
22                  quality of the study as far as the  
23                  size in order to be able to answer the  
24                  question being asked. Those are the  
25                  kinds of things that you look at.

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1                   And then also the question --  
2                   when you're looking at a specific  
3                   question, you may pull in -- like you  
4                   asked me about the starch particle.  
5                   You may pull in things that you give  
6                   less weight because obviously that's  
7                   not just talc, that's starch, and you  
8                   have to consider that. So that is  
9                   part of the process.

10          QUESTIONS BY MS. BRANSCOME:

11          Q.       Dr. Plunkett, the question I  
12         asked you simply was: The paper that you  
13         reference that contains some detail about the  
14         Canadian analysis, that was published after  
15         you completed your report that's marked here  
16         as Exhibit 4; is that correct?

17                   MR. MEADOWS: Objection.

18                   THE WITNESS: Yes, and I  
19         believe I answered that at the start.  
20         I usually try to answer your question,  
21         and then I try to explain further some  
22         details I think are important context  
23         on my answer.

24          QUESTIONS BY MS. BRANSCOME:

25          Q.       I understand that,

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1 Dr. Plunkett. You have given many  
2 depositions. You understand I can ask you  
3 for more detail if that would be helpful to  
4 me.

5 If you could, just focus on the  
6 question that I asked, and we can explore  
7 additional areas if that's something I'm  
8 interested in doing.

9 Okay?

10 MR. MEADOWS: Objection.

11 She's --

12 MS. BOCKUS: Break?

13 MR. MEADOWS: After I finish my  
14 objection.

15 She's going to answer the  
16 question as thoroughly as she feels  
17 like she needs to answer the question  
18 based on the way you ask it.

19 Want to take a break now?

20 MS. BRANSCOME: We can go off  
21 the record.

22 VIDEOGRAPHER: We're going off  
23 the record at 10:41 a.m.

24 (Off the record at 10:41 a.m.)

25 VIDEOGRAPHER: We are back on

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1                   the record at 10:56 a.m.

2       QUESTIONS BY MS. BRANSCOME:

3                   Q.       All right. Dr. Plunkett, we  
4       started talking a little bit about the CIR  
5       analysis that was done in 2013.

6                   Am I correct you no longer  
7       consider that reliable? Is that your  
8       opinion?

9                   A.       Yes.

10          Q.       Okay. And you identify in your  
11       report marked as Exhibit 4, I believe it's  
12       paragraph 56?

13          A.       Yes, that's correct. And I  
14       think I talked about it later on as well, but  
15       definitely I do here.

16          Q.       Okay. And in paragraph 56, you  
17       state that the CIR panel failed to account  
18       for all the studies that informed on the  
19       issue of migration of particles such as talc  
20       upwards through the reproductive tract.

21                   Is that your opinion?

22          A.       Yes.

23          Q.       Okay. And then you state that  
24       because of that you assign, quote, little  
25       weight to the conclusions reached by the CIR

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1 panel; is that correct?

2 A. Yes.

3 Q. And so is it your view that a  
4 study or an analysis that reaches a  
5 particular conclusion should be assigned  
6 little weight if it fails to consider all  
7 relevant scientific evidence to the issue  
8 that it's evaluating?

9 MS. PARFITT: Objection.

10 THE WITNESS: I think it  
11 depends on the situation, but that  
12 could be the case, yes. It depends  
13 on -- on the -- depends on -- I think  
14 it would depend on each case, the  
15 question being asked, and what was  
16 omitted. But, yes, I think it could.

17 QUESTIONS BY MS. BRANSCOME:

18 Q. Okay. And in this situation  
19 you identify -- I believe you claimed that  
20 eight human studies were not considered by  
21 the CIR 2013 panel; is that correct?

22 A. Let me look at the number, but  
23 that sounds about right. Yes.

24 Q. All right. And returning,  
25 actually, to your prior answer, you said that

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1 the failure to consider all relevant  
2 scientific evidence on a topic would lead you  
3 to assign little weight to a particular  
4 conclusion. You said that that could happen.

5 Under what circumstances would  
6 you assign a conclusion little weight for  
7 failing to consider what you consider to be  
8 all relevant pieces of scientific literature?

9 A. Well, I think it depends --  
10 well, the reason I specifically addressed  
11 that in this case is because that was -- the  
12 conclusions about migration is the main  
13 reason why the CIR panel then draws  
14 additional conclusions later on.

15 So my issue is, migration was  
16 key to what -- the decisions they made about  
17 the safety issues of talc. And so in that  
18 particular case, this -- this failure to  
19 consider all the evidence was extremely  
20 important, in my view, and I gave it little  
21 weight.

22 There might be a situation  
23 where some -- for example, you may only look  
24 at six or eight studies, even though there  
25 may be dozens out there. You may have a

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1 reason for why you only looked at six or  
2 eight, or it may be -- and as a result you  
3 may lay that out and, therefore, you may  
4 still give weight to conclusions drawn. Or  
5 it may be that the six or eight are --  
6 studies that you discuss are not -- the  
7 weight is not affected by what you've  
8 omitted.

9 I believe that the weight is  
10 affected by what is omitted when you look at  
11 some of the articles being review articles,  
12 which give you an understanding of what was  
13 generally accepted within the scientific  
14 community when you get to reviews, those  
15 kinds of things. So it really is a  
16 case-by-case basis.

17 But certainly I do believe that  
18 it is possible that in another circumstance  
19 where things are omitted you would come to  
20 the same conclusion, that you give those  
21 conclusions less weight.

22 Q. Is there a way, if someone were  
23 try to replicate the weighting of particular  
24 evidence based upon your process, for them to  
25 know whether or not the omission of a

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1 citation of certain studies means that a  
2 study should be given little weight or  
3 whether it wouldn't affect the weighting of  
4 that scientific article?

5 MS. PARFITT: Objection. Form.

6 THE WITNESS: So I think this  
7 is the issue of judgment, training and  
8 experiencing that is applied to all  
9 such assessments, and this is why  
10 different scientists may come to  
11 different conclusions. But certainly  
12 it is -- it was important to my  
13 assessment on this issue because of  
14 the prominent role that the CIR report  
15 gives to their conclusions here for  
16 why they then drew conclusions about  
17 safety. And so that link was  
18 extremely important.

19 MS. BRANSCOME: Can we pause  
20 for just a moment?

21 VIDEOGRAPHER: We are going off  
22 the record at 11:00 a.m.

23 (Off the record at 11:00 a.m.)

24 VIDEOGRAPHER: We are back on  
25 the record at 11:01 a.m.

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.        Okay. Of the eight studies  
3       that you identify on page 37 of your report  
4       that you contend the CIR panel did not  
5       account for, do any of those eight studies  
6       specifically discuss the migration of talc in  
7       human subjects?

8           A.        No, I don't believe they do,  
9       but there are a couple of these studies that  
10      I found to be extremely important if you want  
11      me to explain that to you.

12          Q.        Do you break out in your report  
13      in any other paragraphs which of these eight  
14      articles you consider to be extremely  
15      important?

16                  And if you could just point me  
17      to paragraph numbers, that's good enough if  
18      you have, in fact, broken them out.

19          A.        I have. I -- this whole  
20      section I break -- I talk about each one  
21      individually. So I think you can tell by  
22      what I read -- what I'm discussing what I  
23      thought was important and informative about  
24      each of those.

25          Q.        Do you rank the eight studies

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1      in any way by their importance to you?

2            A.       Not with any numerical rank,  
3      no, but certainly I think I do that for you  
4      when I talk about the studies. I give you an  
5      understanding of ones that I think are  
6      particularly informative and ones that are  
7      not.

8                   So, for example, I weight the  
9      human data -- I think I tell you that -- more  
10     than the animal data because of the  
11     differences between the reproductive tracts  
12     of humans versus animals generally, upright  
13     versus -- upright and habits and things that  
14     humans do that relate to insertions in and  
15     out of the reproductive tract, I guess is a  
16     nice way to describe it, versus an animal,  
17     that those can have, and then also the  
18     differences between animals and humans in  
19     terms of bursal sac around the ovary, those  
20     kinds of things.

21                  So I do -- that -- I guess that  
22     ranking I do give you here. I tell you that  
23     I think these -- I think that the most  
24     relevant are going to be the human studies  
25     versus the animal studies.

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1 Q. Right.

2 So my question specifically is,  
3 where would you point me to in your report to  
4 understand the weight that you gave each of  
5 these particular eight studies?

6 A. At my descriptions of those  
7 studies and what I describe. That's all I  
8 can tell you.

9 Q. And I'm just asking,  
10 Dr. Plunkett, can you point me in the report  
11 to where that discussion takes place?

12 A. It takes place -- I have a  
13 discussion for each study, and I would -- and  
14 if you read what I say about each study, I  
15 try to go through what the strengths and  
16 weaknesses of those studies are.

17 And so those -- that would be,  
18 let's see -- you want me to give you the  
19 starting paragraph?

20 Q. So, for example, Parmley and  
21 Woodruff. Can you point me to where in your  
22 report you discuss Parmley and Woodruff, such  
23 that I can understand the weight that you  
24 gave that particular study?

25 A. So the year of it is...

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1                   So I think I discuss it in  
2 paragraph 44, and so I describe for you what  
3 important information is in there, which is  
4 the information that I take as forming part  
5 of my weight of the evidence.

6                   So one of the most important  
7 things is what -- they have a figure they  
8 show, and they're showing -- which is one of  
9 the unique figures in all of the published  
10 literature. But it talks about the  
11 differences between the female reproductive  
12 tract and the male reproductive tract, and it  
13 shows the actual -- it talks about a  
14 discussion of movement from substance in the  
15 environment through -- into the vagina, into  
16 the fallopian tubes. So it's a paper that  
17 addresses that very specific issue.

18                 Q.         So my question to you, though,  
19 is, where do you have a discussion of the  
20 weight that you give to these particular  
21 articles?

22                 A.         So the discussion of the weight  
23 has to do with the information described. I  
24 don't give them a numerical ranking. I told  
25 you that.

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1                   So what I do is, when I'm  
2 discussing about these -- all of these papers  
3 here contribute to my weight of the evidence.  
4 And if it's a human study, I'm giving those  
5 more weight than I'm giving animal studies.  
6 And that's described.

7                   And then within papers I'm  
8 pulling out information that contributes to  
9 what I think is important about what the  
10 study says, and that -- and the importance of  
11 what is described within the study  
12 contributes to my weight.

13                  And I don't know how else to  
14 describe it to you. That is the process that  
15 scientists go through when they evaluate  
16 data.

17                  Q.        And so my question to you:  
18 Earlier you said of these eight studies, some  
19 of them were particularly important to you.

20                  How would I, using only what's  
21 written in your report, understand which of  
22 those eight studies was of particular  
23 importance to you?

24                  A.        So it would have to do with  
25 what I discuss about the study. So I'm

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1 telling you, when I -- if you look through  
2 this entire section, this is the Parmley and  
3 Woodruff paper. It is important because it  
4 addresses the specific issue of movement of  
5 environmental substances from the outside to  
6 the inside. So I'm giving that importance in  
7 my evaluation because of what that author is  
8 actually discussing.

9 I don't know how else to  
10 describe that. I apologize. I mean, to me,  
11 weight of the evidence is a process that  
12 scientists use bringing their training and  
13 experience and judgment, and it's not a  
14 numerical process across the board, it just  
15 is not, based on the way weight of the  
16 evidence is used within science.

17 Q. Now, Dr. Plunkett, though, you  
18 would acknowledge that if you wanted to  
19 assign numerical values to the studies, that  
20 has been something that has been done by  
21 other authors and other authors on whom you  
22 rely, correct?

23 MS. PARFITT: Objection. Form.

24 THE WITNESS: I don't believe  
25 that's true. I'll need to look -- I

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1           don't believe that's true with respect  
2           to the biological information. I  
3           believe it may be true with respect to  
4           the epidemiology studies.

5           You want me to look real quick  
6           to confirm that? I can do that really  
7           quick, but...

8       QUESTIONS BY MS. BRANSCOME:

9           Q.       I'm simply saying, could you  
10          assign a numerical value if you chose to do  
11          so?

12          MR. MEADOWS: Objection.

13          Objection. Form.

14          THE WITNESS: And I'm -- what  
15          I'm trying to say to you is I think  
16          that I -- that there is no one set of  
17          rules that you would assign in order  
18          to do that for all the types of  
19          studies that you weigh.

20          I would agree that I have seen  
21          it routinely done -- well, not  
22          routinely, but I've seen it done  
23          within the epidemiological community  
24          when they go through the epi data.

25          But not -- it's not something that

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1 I've seen done when you talk about  
2 weight of the evidence as part of a  
3 human health risk assessment. That is  
4 not something that scientists  
5 typically do as far as giving  
6 numerical rankings.

7 QUESTIONS BY MS. BRANSCOME:

8 Q. You're familiar with the  
9 National Cancer Institute, correct?

10 A. Yes, I am.

11 Q. All right. They are considered  
12 to be the nation's leader in cancer research,  
13 correct?

14 MS. PARFITT: Objection to  
15 form.

16 THE WITNESS: The National  
17 Cancer Institute?

18 Yes, they are. I don't know if  
19 they're "the" leading, but they're one  
20 of the leading, that's true.

21 QUESTIONS BY MS. BRANSCOME:

22 Q. Okay. And you're familiar with  
23 publications that they issue called physician  
24 data queries?

25 A. Yes, I am.

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1 Q. All right. And you are aware  
2 that there is, in fact -- called PDQs,  
3 correct?

4 A. That's the abbreviation, yes.

5 Q. Right. And you're aware that  
6 the National Cancer Institute has in fact  
7 published a PDQ that addresses a potential  
8 connection between talc and ovarian cancer,  
9 correct?

10 A. I'm aware of several that have  
11 been done over the years, but, yes, I'm aware  
12 of that.

13 Q. And have you reviewed those?

14 A. Yes, I have.

15 Q. Are they listed on your  
16 reliance list?

17 A. No, but they're listed within  
18 the materials as discussed within my  
19 depositions, and I thought -- and my  
20 testimony. I thought that was part of my  
21 reliance list. I believe that it -- it was  
22 in my reliance list, is encompassing all of  
23 the testimony as well as the actual  
24 documents. Maybe I'm mistaken, but that was  
25 my understanding.

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1           Q.        Okay. If they are not on your  
2 reliance list, should they be?

3           A.        I believe that they are on my  
4 reliance list by it having been pointed to as  
5 part of the testimony that I have given and  
6 the documents that I have relied upon during  
7 testimony.

8           Q.        Okay. And you are aware that  
9 they have issued a PDQ that -- on the website  
10 as of today, correct?

11          A.        I haven't looked today, so I'm  
12 sure -- but I know that -- I don't believe it  
13 has been removed, so I believe that there is  
14 something there, yes.

15          Q.        All right. And what is your  
16 understanding of the position stated in the  
17 PDQ with respect to a possible link between  
18 talc and ovarian cancer?

19          A.        So I'd have to look at the one  
20 today to tell you what it says, but it's  
21 evolved over time and it's changed over time,  
22 and I have specific opinions that I've  
23 expressed at trial about that issue.

24                   Do you want me to go into that  
25 details or I mean --

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1           Q.       I'm not asking about your  
2     opinions about what their position is. I'm  
3     simply asking you, Dr. Plunkett, the most  
4     recent NCI PDQ that you have reviewed, what  
5     is the position that the National Cancer  
6     Institute has taken with respect to the  
7     relationship between talc and ovarian cancer?

8           A.       So I would want to pull it out  
9     to give you the specific statement of their  
10   position, but their position has changed such  
11   that later in time they've weakened the  
12   link -- their statements about the link  
13   between ovarian cancer and genital talc use.

14           So it used to be seen as a  
15   cause, and now I believe it's not seen as a  
16   cause. I don't know the exact language,  
17   though. I'd have to look at it as -- maybe  
18   risk factor is the better word to use.

19           And I need to look at the most  
20   recent one. And that would be the best way.  
21   Let's just see what it says.

22           Q.       'Cause is it your  
23   position as you sit here today that the  
24   National Cancer Institute has ever issued a  
25   statement that talc causes ovarian cancer?

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1                   A.         I believe it was listed as a  
2 risk factor for ovarian cancer in the older  
3 PDQs.

4 (Plunkett Exhibit 7 marked for  
5 identification.)

6 QUESTIONS BY MS. BRANSCOME:

7 Q. I do have a copy here. Just  
8 for the sake of the record, we will mark this  
9 as Plunkett Deposition Exhibit Number 7.

10 Handing a copy to you,  
11 Dr. Plunkett, do you recognize the document  
12 that I just handed you that's marked as  
13 Exhibit 7?

14 MR. LOCKE: What's the date of  
15 that?

16 MS. BRANSCOME: This was  
17 printed on December 14, 2018.

21 MR. LOCKE: Yes, thank you.

22 THE WITNESS: I have seen this  
23 one, yes.

24 QUESTIONS BY MS. BRANSCOME:

Q. All right. And you can review

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1 any -- whatever portion of this is helpful to  
2 you.

3 And then if you could answer my  
4 question, Dr. Plunkett, of what is the  
5 position as stated in Deposition Exhibit  
6 Number 7 of the National Cancer Institute  
7 with respect to the relationship between talc  
8 and ovarian cancer?

9 A. So I would be looking at the  
10 section on page 12 of 18, and maybe you're  
11 looking somewhere else, but that's where they  
12 actually talk about perineal talc exposure.  
13 And it's under the section where they have  
14 now moved into factors with an adequate  
15 evidence of an association and they describe  
16 it here. So they're calling it an  
17 association where the weight of the evidence  
18 is not adequate to support that association.

19 Q. All right. And so the first  
20 sentence of the section under perineal talc  
21 exposure states, "The weight of the evidence  
22 does not support an association between  
23 perineal talc exposure and an increased risk  
24 of ovarian cancer."

25 Did I read that correctly?

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1 A. You did read that correctly.

2 Q. All right. And it indicates  
3 that "results from case-control and cohort  
4 studies are inconsistent."

5 Did I read that correctly,  
6 Dr. Plunkett?

7 A. You did.

8 Q. And the question that I would  
9 ask simply is, do you discuss the National  
10 Cancer Institute PDQ in the report that  
11 you've issued in the MDL, which is identified  
12 as Exhibit 4?

13 A. I don't specifically discuss  
14 this document, no, I do not.

15 Q. Okay. And you understand that  
16 the NCI PDQ did a weight of the evidence  
17 analysis that followed a formal evidence  
18 ranking system, correct?

19 MS. PARFITT: Objection.

20 THE WITNESS: So I -- it's not  
21 laid out here, but they do have a  
22 process they use.

23 Is that what you're asking me?

24 QUESTIONS BY MS. BRANSCOME:

25 Q. Yes.

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1           A.       Yes. And again, they're  
2 ranking the epidemiological data, and so I  
3 understand that that is there, yes.

4           Q.       Now, you've said a few times  
5 that you could qualitative -- you could give  
6 a quantitative weight to an epidemiological  
7 study, somehow suggesting that it is  
8 different from other types of studies.

9                   What is it about a  
10 toxicological study, for example, that would  
11 prevent someone from giving a quantitative  
12 weight in a weight of the evidence analysis?

13          A.       Because it is just what is  
14 typically done and not done. There are  
15 certain practices within the community, what  
16 is kind of -- I would say that scientists use  
17 routinely, or scientists have used. Not all  
18 scientists give numerical rankings to  
19 epidemiological data either, because even  
20 within a Bradford Hill assessment, when you  
21 use the considerations, there's no  
22 requirement for ranking studies in order to  
23 meet the requirements of use of that  
24 methodology.

25          Q.       Okay.

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1           A.       But I have seen it done in the  
2 epidemiology community, and that is the most  
3 common place I see it. I do not see other  
4 toxicologists that are assessing animal  
5 studies and in vitro studies doing it that  
6 same way.

7           When you do a human health risk  
8 assessment, that isn't routine practice to do  
9 numerical rankings on studies.

10          Q.       Okay.

11          A.       At least in my experience and  
12 in my training, and I was trained in the use  
13 of risk assessment by one of the individuals  
14 who actually invented the process.

15          Q.       Okay. Okay. But do you  
16 consider the epidemiological evidence as part  
17 of your risk assessment in the MDL?

18          A.       I do, because I'm looking at it  
19 in the context of what is out there and  
20 what's available. I don't always have human  
21 data when I do risk assessments, but in this  
22 one I do. So I do consider them, yes.

23          Q.       Okay. Did anything prevent you  
24 from doing a quantitative assessment of the  
25 weight that you were giving different pieces

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1 of epidemiological evidence?

2 A. If by -- you mean prevent, was  
3 someone stopping me from doing that, no. But  
4 if you ask what would be standard practice  
5 based on my experience, I would not be doing  
6 that.

7 Q. Has anyone -- and I'm not  
8 referring in this case to any attorneys. But  
9 has anyone reviewed your -- the weighting  
10 that you gave specific pieces of evidence as  
11 essentially a form of a peer review process?

12 A. If by that you mean have I  
13 submitted my opinions for publication, no, I  
14 have not done that. Part of -- that's partly  
15 driven by my understanding of the evidence  
16 that I reviewed, that some of it may not be  
17 something that I should be discussing  
18 necessarily in a public form outside of the  
19 cases I'm working in.

20 But certainly I have not  
21 submitted it for publication, if that's what  
22 you mean. No, I have not done that.

23 Q. Okay. Has the methodology that  
24 you have used in the MDL, has that been --  
25 have you submitted any type of analysis using

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1       that methodology for publication even outside  
2       of particularly looking at Johnson's baby  
3       powder, for example?

4           A.       Yes, in -- if you look at my  
5       publications that describe risk assessments  
6       that I have done. So the one that would come  
7       to -- to play that's similar as far as the  
8       scope of the weight of the evidence would --  
9       at least with the animal and the in vitro  
10      studies, would be the paper that I published  
11      on copper, looking at the database of copper  
12      and identifying points of departure and  
13      target organs and risk -- risk issues based  
14      on copper use in humans, trying to set a --  
15      understand what a safe exposure level could  
16      be to copper in water. And that was  
17      published -- that actually was one of the  
18      papers that's published with Dr. Krewski, who  
19      is one of the authors of this risk assessment  
20      in Canada.

21           Q.       And is it your position that  
22       you follow the same methodology in what  
23       you've reported in the MDL with respect to  
24       Johnson's baby powder that you did in your  
25       analysis of copper?

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1                   A.         Yes, with the process of going  
2 through all of the publicly available  
3 information, putting it together based on its  
4 relevancy and reliability.

5                   We did a process where we  
6 grouped it based on animal versus human, just  
7 like I've done here. And we call it the  
8 bins, but it's the same idea. I have a bin  
9 of human idea, I have a bin of animal data  
10 and a bin of in vitro data. And so, yes, the  
11 process was very, very similar.

12                  Q.         Okay. Returning back to some  
13 documents that you chose not to cite in your  
14 report, you do not discuss the Gonzales 2016  
15 study in your report for the MDL, correct?

16                  MS. PARFITT: Objection. Form.

17                  THE WITNESS: I'll have to  
18 look. It is not cited in the  
19 reference list to my report, that is  
20 true. So that means it would not be  
21 mentioned specifically in the body of  
22 the report.

23                  QUESTIONS BY MS. BRANSCOME:

24                  Q.         You're familiar with the  
25 Gonzalez 2016 study, correct?

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1           A.       If you want me to talk about  
2     it, you'd have to pull it out for me, but I  
3     know the name, yes.

4           Q.        Okay. And it was looking at an  
5     association between the perineal use of talc  
6     and ovarian cancer, correct?

7           A.        That, I'd have to look at it to  
8     tell you. I believe it was a human study  
9     that would be consistent with that, but I  
10    need to pull it out to look at it.

11          Q.        All right. Do you, as you sit  
12    here today, do you know why you did not  
13    discuss it in your report?

14          A.        I wasn't doing a full causation  
15    analysis in this report, so as a result I'm  
16    not trying to characterize every piece of  
17    human data. But I certainly am looking at  
18    the consistency across the studies, and  
19    that's what I've done.

20               And I mention it here. I do  
21    think I mention here that there are studies  
22    that came to different conclusions than the  
23    ones that I'm specifically describing.

24          Q.        Okay. And so why is it that --  
25    why is it acceptable for you to choose not to

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1 include something like the Gonzales 2016  
2 study, but yet you will disagree the  
3 2013 -- the CIR 2013, you will give it little  
4 weight for not discussing particular studies?

5 A. So that's a very different  
6 exercise. You want me to explain my thinking  
7 on that? I can do that for you, but I  
8 believe that's apples and oranges question.

9 My reasons for giving little  
10 weight to the CIR overall assessment versus  
11 my weight or the assessment I make of an  
12 individual piece of data, that's different.  
13 And that's what you're describing for me.

14 And I believe Gonzales is in my  
15 overall reliance list, so I have read  
16 Gonzales. It is something that I have  
17 considered; it's not something that I've  
18 cited in my paragraphs. So it doesn't mean  
19 it didn't go into my weight of the evidence,  
20 because I do have it and I have reviewed it.  
21 I just don't recall the details on it.

22 Q. Is it your position as you sit  
23 here today that you know for sure that the  
24 CIR panel did not -- was not aware of or even  
25 considered any of the eight studies that you

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1 contend the omission of which makes it of  
2 little weight?

3 MS. PARFITT: Objection. Form.

4 THE WITNESS: I would say I'm  
5 99.9 percent sure, based on the  
6 process that is -- that goes in. And  
7 if you want me to explain, I'll tell  
8 you why I feel that level of surety.

9 You know, I can always say that  
10 maybe there was someone that came to  
11 the panel that did a search on their  
12 own, but that is not what's done. The  
13 individuals that come to the panel are  
14 given a body of information provided  
15 to them in written form that they  
16 review. So it's not like they -- they  
17 have access to anything that isn't  
18 cited in the actual report.

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Okay. The eight articles that  
21 you discuss that are not mentioned in the CIR  
22 panel's work, they are publicly available  
23 pieces of scientific literature, correct?

24 A. Yes, which was why it's  
25 interesting to me that those were not grabbed

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1 and included within -- within the assessment  
2 done by the -- by the PCPC's group that  
3 handles CIR -- handled the CIR process here.

4 Q. Okay. We received just before  
5 your deposition, a few days in advance, a  
6 list of materials that have been added to  
7 your reliance list since you produced your  
8 report in this case.

9 Did you provide that list of  
10 materials to counsel to -- are you aware of  
11 the materials that were identified?

12 A. Yes, I am. They're ones that I  
13 have reviewed since my report and -- yes,  
14 which would have been, I believed, important  
15 for you to know about, because obviously you  
16 wouldn't know if I hadn't provided that to  
17 you, and fair game for you to ask me about.

18 Q. On that list was contained a  
19 number of news articles.

20 A. Uh-huh.

21 Q. Are news articles pieces of  
22 scientific information that you typically  
23 consider in performing a risk assessment?

24 A. No, they're not part of my risk  
25 assessment, but they -- but they were

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1 relevant to -- they were relevant to my  
2 overall assessment of the issue of what the  
3 company is doing with regard to public  
4 dissemination of information.

5 So it's not the risk assessment  
6 part. It's more on the issue of the -- when  
7 I talk about the different influences of the  
8 company on public dissemination of  
9 information, I went through the different  
10 specific issues. So this would be a specific  
11 issue related to a news report that someone  
12 comes out with, the Reuters report, and then  
13 looking at what the company is saying in  
14 addition to that.

15 So it's understanding -- for  
16 example, the documents that Reuters  
17 discusses, many of those I'm sure I have  
18 seen, although I don't have access to -- I  
19 wasn't able to go on websites and download  
20 everything that they cite. But certainly  
21 they looked familiar, some of the ones I did  
22 see.

23 So it's that issue of -- the  
24 last part of my report, I think. Want me to  
25 tell you the section? It would be in the

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1 section on the role of the industry in  
2 Section 7.

3 Q. Okay. So the newspaper  
4 articles are not something that you are  
5 considering as part of your analysis of  
6 whether there is a risk of ovarian cancer  
7 from Johnson's baby powder, correct?

8 A. No, that's a separate issue  
9 because it's not -- it's not scientific data,  
10 per se.

11 Q. Okay. All right. Now, if you  
12 could turn to paragraph 31 in your report.

13 Okay. You discuss the  
14 biological effects of talc in this paragraph  
15 and in others, correct?

16 A. Yes, I would call this my  
17 introductory paragraph to transition into a  
18 specific topic, yes.

19 Q. Okay. And you talk here about  
20 the structure and size of talc affecting its  
21 properties.

22 What do you mean by that?

23 A. So whether it's fibrous enough,  
24 platy, fibrous. Whether it is particle sizes  
25 of less than 10 microns, less than 5 microns,

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1 greater than 75 microns. There's  
2 different -- certain pieces of literature  
3 deal with different size ranges of talc. The  
4 smaller the size range, the more toxic it is,  
5 for example, to lung tissue; the more likely  
6 it is to be able to move, based upon the  
7 size, versus being engulfed by a macrophage  
8 if it's a larger particle, things like that.

9 Q. So focusing specifically on  
10 ovarian cancer, what role does size and  
11 structure of a talc particle play with  
12 respect to a risk of ovarian cancer in your  
13 opinion?

14 A. I don't think I formed a  
15 opinion that it has to be a specific size or  
16 structure, because the -- my opinions are  
17 related to the fact that we have a complex  
18 mixture of ingredients within the body  
19 powder, and my assessment's been on the  
20 overall consumer product, not on any one  
21 particular ingredient only within it.

22 So it's the idea of just  
23 understanding that size and structure of  
24 these particles are general principles that  
25 affect toxicology. So a larger particle or a

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1 fibrous particle may have a different tissue  
2 toxicity response than a smaller particle.

3 So in other words -- I think I  
4 discuss this later in a paragraph about  
5 pleurodesis, the idea that you can get acute  
6 versus chronic inflammation, or respiratory  
7 distress or not. So it's just this idea of a  
8 general principle that outlines how you would  
9 think about particles generally as a  
10 toxicologist.

11 Q. Well, okay. So you said that  
12 your assessment is based on the overall  
13 consumer product. That would be Johnson's  
14 baby powder or SHOWER TO SHOWER®, correct?

15 A. Yes.

16 Q. All right.

17 A. Or Shimmer. I think that's the  
18 other name. There's a third product.

19 Q. Okay. But my question to you  
20 is, you actually cite a number of pieces of  
21 literature in the section about the alleged  
22 toxicity of talc that don't relate to the  
23 overall consumer products at issue in this  
24 case, correct?

25 MS. PARFITT: Objection. Form.

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1                   THE WITNESS: No, I would  
2                   disagree with that when you use the  
3                   word "relate." Relate to me means is  
4                   it relevant to the assessment, and  
5                   they are, even if they're not just on  
6                   the finished product.

7                   But if what you mean is that  
8                   there are studies that did not test  
9                   the consumer product but individual  
10                  ingredients or -- that is true, yes,  
11                  but all of that is relevant or relates  
12                  to the overall risk assessment.

13                  QUESTIONS BY MS. BRANSCOME:

14                  Q.        Okay. So given your view that  
15                  information about the individual constituents  
16                  is relevant to evaluating the overall  
17                  toxicity of the ultimate consumer products,  
18                  then my question to you is: How does the  
19                  structure and size of the component talc  
20                  particles play a role in toxicity with  
21                  respect to ovarian cancer?

22                  A.        Just generally -- it's not  
23                  just -- well, with respect to ovarian cancer,  
24                  we start with irritation, inflammation  
25                  potential. Size of particles and shape are

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1 known to affect tissue toxicity as far as  
2 adverse events like inflammation and/or  
3 irritation.

4 Q. Okay. So that's -- that's what  
5 I'm trying to understand in more detail.

6 What is your opinion with  
7 respect to -- let's take size to start with.  
8 Is there a particular size talc particle that  
9 is more or less likely to cause inflammation,  
10 in your opinion?

11 A. It depends whether you're  
12 talking about acute or chronic. I would say  
13 for acute inflammation the larger particles,  
14 such as some of the particle sizes that are  
15 used in the pleurodesis products, are more  
16 likely to initiate an acute inflammatory  
17 response due to the fact that they're large  
18 enough that the body will recognize them with  
19 a fairly robust foreign body response.

20 Q. What is your definition of  
21 large?

22 A. So the literature varies, but  
23 certainly particles that are above -- some of  
24 the literature talks about particles that are  
25 in the range of 25 to 75. Some of them talk

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1 about larger particles even than that.

2                   It has to do with the fact  
3 that -- this is complicated by the fact that  
4 any consumer product -- or any talc sample  
5 will have a range of sizes because they don't  
6 select for one size. They select for smaller  
7 than. So a 200 mesh, a 400 mesh, that has do  
8 with what will filter through.

9                   So pleurodesis, they try to  
10 avoid for those products the really small --  
11 large amounts of less than 10 because that  
12 leads to respiratory distress, whereas many  
13 of the consumer talc products are using much  
14 smaller, finer particles to get that feel and  
15 performance they want from the consumer body  
16 powders.

17                 Q.        Have you reviewed -- focusing  
18 specific on Johnson & Johnson's products,  
19 have you reviewed the documents that relate  
20 to the specifications for the Johnson's  
21 products with respect to the size of the  
22 plate particles?

23                 A.        I have seen those, yes. I  
24 can't tell you what each of them says without  
25 pulling them out, but, yes, that is certainly

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1 documents I have seen and relied upon.

2 Q. Is it consistent with your  
3 understanding that it was Johnson & Johnson's  
4 intention to select large platy talc  
5 particles for its products?

6 MS. PARFITT: Objection to  
7 form.

8 QUESTIONS BY MS. BRANSCOME:

9 Q. Have you seen that in the  
10 documents?

11 A. I don't know that it's  
12 described quite that way, but they certainly  
13 were doing a 200 mesh selection. So -- for  
14 their body powders products. So -- and they  
15 were trying -- and they did make attempts to  
16 look for sources that were more platy talc  
17 than other forms, but that doesn't ensure  
18 that everything is platy talc.

19 Q. Are you familiar with the term  
20 "fines"?

21 A. Yes, generally, but I'm not --  
22 but I'm not an expert in the processing of  
23 talc as far as how you would go about  
24 choosing an ore or a mine. There's others  
25 that will be addressing that. That's not my

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1 area.

2 Q. What is your understanding of  
3 the term "fines"?

4 A. My understanding of the term  
5 "fines" has to be looking for a sample or a  
6 group that has been processed such that it  
7 has certain characteristics.

8 Other than that, I would refer  
9 you to the individuals in litigation that are  
10 going to be dealing with the processing.

11 Q. Okay. Have you taken into  
12 account in your analysis in any way the  
13 beneficiation process that occurs between the  
14 time that the talc is mined and it ends up in  
15 one of the consumer products that is relevant  
16 to your analysis?

17 MR. MEADOWS: Objection.

18 THE WITNESS: So what do you  
19 mean by taking it into account? Am I  
20 aware that they have something that's  
21 in place for that? Yes.

22 But take into account, what do  
23 you mean by that?

24 QUESTIONS BY MS. BRANSCOME:

25 Q. Are you familiar with the

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1 effects that beneficiation can have on the  
2 level of the component -- the components in  
3 talc and what ultimately ends up in one of  
4 Johnson & Johnson's consumer products?

5 MR. MEADOWS: Objection.

6 THE WITNESS: So I'm not -- I'm  
7 not familiar with all the details, but  
8 I am familiar that it is a process  
9 they're using to attempt to result in  
10 a product that has characteristics  
11 that would be desirable for a consumer  
12 product.

13 Again, there is my  
14 understanding that others are going to  
15 be discussing the geology or the  
16 processing, and that is not something  
17 I'm looking at.

18 The literature as it relates to  
19 what has been tested in the public  
20 literature in particular, and that  
21 would be either an ingredient or a --  
22 or a consumer product or a -- they may  
23 discuss exposure occupationally to  
24 mining or milling, which is -- which  
25 is an issue that you can consider when

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1                   you're reviewing that literature as  
2                   well.

3                   QUESTIONS BY MS. BRANSCOME:

4                   Q.         Okay. And so when you cite --  
5                   for example, you have a significant number  
6                   of -- I'm trying to find the right paragraph.

7                   You have a section in your  
8                   report where you discuss a number of  
9                   different articles that relate to talc, and  
10                  in parentheses you identify that the talc  
11                  source might be cosmetic, it might be  
12                  industrial, things of that nature, correct?

13                  A.         Yes, I do that on purpose  
14                  because I wanted -- I did look at the  
15                  literature to understand what they were --  
16                  what they were -- what type of exposure they  
17                  were describing.

18                  Q.         Okay. And so understanding  
19                  that some of those products are not  
20                  representative of what ultimately is in  
21                  Johnson's baby powder, do you have anything  
22                  in your report that explains how you did or  
23                  did not give weight to those particular  
24                  studies?

25                   MS. PARFITT: Objection. Form.

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1                   THE WITNESS: Let me look and  
2                   see what I say.

3                   If the question has to do with  
4                   numerical rankings, no, I did not do  
5                   that. But you're asking something  
6                   else, right, broader than that,  
7                   correct?

8                   QUESTIONS BY MS. BRANSCOME:

9                   Q.         The question that I have is,  
10                  how did -- is there somewhere in this report  
11                  that I can understand the weight that you  
12                  assigned to say a study that related to  
13                  industrial talc as opposed to information  
14                  about cosmetic talc, for example?

15                  MR. MEADOWS: Objection.

16                  THE WITNESS: So I -- I'm -- I  
17                  believe I address that. I don't know  
18                  it's exactly answering your question,  
19                  but I lay out for you the  
20                  characteristics of the literature in  
21                  paragraph 37, and I point out that the  
22                  scientific literature varies.

23                  And the fact -- and I point --  
24                  and I admit -- I'm not admitting. I'm  
25                  stating the fact that in some cases

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1           the authors will not describe it  
2           specifically as the type of talc, but  
3           just talc, whereas -- with no  
4           description of purity or state, for  
5           example. But in cases where the  
6           literature does, I did consider that  
7           in my weight of the evidence.

8                 So, for example, when I -- when  
9                 I lay it out here in these bullets  
10               where I'm putting for you tremolite  
11               mining industrial grade cosmetic, it  
12               certainly is something that I weighed.  
13               And obviously as much information as I  
14               can get on cosmetic-grade talc is  
15               going to be most important in the  
16               assessment, but that doesn't mean the  
17               other information isn't relevant.

18               You want me to explain why?

19       QUESTIONS BY MS. BRANSCOME:

20       Q.       Well, so, for example, you  
21       describe the Dreessen article that related to  
22       trimellitic talc that's mined out of  
23       New York.

24               You would agree that  
25       trimellitic talc from New York is not

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1 something that ever ended up in Johnson's  
2 products, correct?

3 MR. MEADOWS: Objection.

4 THE WITNESS: I don't think I  
5 can answer that yes or no. I haven't  
6 done an assessment to see whether it  
7 ever ended up in the products. That's  
8 a different question.

9 I certainly am aware of the  
10 fact that was not a primary source of  
11 their talc, that is true. I do know  
12 that.

13 In other words, I don't have  
14 records from -- going back from 1894  
15 on what the source of their talc was.  
16 So I can't tell you over time.

17 What I do know, what's been put  
18 into depositions and testimony of  
19 company employees more recently, where  
20 it's my understanding that the  
21 principal sources over the years were  
22 either the Vermont mine, the Italian  
23 mine or the Chinese mine. And there  
24 were different interruptions in time  
25 where different mines were used,

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1                  depending on sourcing.

2          QUESTIONS BY MS. BRANSCOME:

3                  Q.       So as part of your expert  
4                analysis where you are evaluating articles  
5                that relate to different types of talc from  
6                different sources of talc, have you done an  
7                analysis of how those particular types of  
8                talc do or do not relate to what is in the  
9                consumer product manufactured by Johnson &  
10               Johnson?

11                 MS. PARFITT: Objection. Form.

12                 THE WITNESS: The first part of  
13                your question, again? I'm sorry.

14                 MS. BRANSCOME: Would you read  
15                it back?

16                 THE WITNESS: Could you read it  
17                back to me again? I didn't mean to  
18                wander, but the first few words I  
19                missed.

20                 (Court Reporter read back  
21                question.)

22                 THE WITNESS: Okay. So I  
23                certainly did, which is why I'm  
24                breaking this out here for you this  
25                way.

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1                   So I am -- I am certainly  
2                   recognizing, and I analyzed on the  
3                   paper -- through the papers what type  
4                   of product, if available, that the  
5                   data is on.

6                   But if you read my report in  
7                   the process of risk assessment, all of  
8                   these categories of papers are  
9                   relevant to telling you something  
10                  about what talc can do. And then when  
11                  you talk about drawing final  
12                  conclusions, I'm looking for  
13                  information, if I can, and I have it,  
14                  that is on point to the product that  
15                  was sold.

16                  So certainly the studies that  
17                  give me information on cosmetic-grade  
18                  talc are extremely important to my  
19                  assessment, and they're ones that I've  
20                  discussed or we've even used in trial  
21                  before when we've talked about putting  
22                  together a timeline.

23                  That's what this is about, by  
24                  the way. This discussion here, I'm  
25                  starting to lay out what information

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1           was available over time, and that's  
2           simply what this is. It's a survey of  
3           the literature that talks about  
4           adverse effects of talc, and if I can,  
5           I separate it into different qualities  
6           or purities.

7        QUESTIONS BY MS. BRANSCOME:

8           Q.       Dr. Plunkett, respectfully, I  
9           don't believe you answered my question.

10           Can you point me to anywhere in  
11          your expert report that's been produced in  
12          this MDL where you do an analysis of how the  
13          different talc types and sources that you are  
14          citing as support for the toxicity of talc  
15          generally relate to the products manufactured  
16          by Johnson & Johnson?

17           MR. MEADOWS: Objection.

18           THE WITNESS: So I don't know  
19          how else to answer that but to tell  
20          you I think that's what this whole  
21          section is about. I step you  
22          through -- I identify different types  
23          of evidence. I identify for you what  
24          was tested in those different pieces  
25          of evidence, and then I step through

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1           that to draw conclusions based upon  
2           what was available for me to assess.

3       QUESTIONS BY MS. BRANSCOME:

4           Q.        Okay.

5           A.        I don't know how else to answer  
6       it for you. That's what the section is meant  
7       to do, and that's why I broke it out that  
8       way. You know, I recognize that there is  
9       data on different things.

10                  What's interesting about even  
11       the data on different things, there's a  
12       common mechanism that is involved with the  
13       type of tissue toxicity you get, and that's  
14       irritation and inflammation. Regardless of  
15       whether it is of a certain grade or not, you  
16       get certain types of adverse reactions. May  
17       be a more sustained reaction with a  
18       industrial grade versus cosmetic grade, but  
19       they all have the capability to produce that  
20       type of adverse effect.

21           Q.        Dr. Plunkett, where can you  
22       point me to in your report that you discuss  
23       the weight that you give studies that relate  
24       to talc from New York as opposed to studies  
25       that relate to cosmetic talc that ultimately

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1 ended up in Johnson's baby powder?  
2 MS. PARFITT: Objection. Form.  
3 THE WITNESS: I've tried to  
4 answer that for you. The weight that  
5 I'm giving -- the weight that I'm  
6 giving is part of my assessment. So,  
7 again, I don't give numerical  
8 rankings. I've answered that for you.  
9 I don't do that.

10 What I instead do is I'm  
11 looking at everything that's relevant,  
12 everything that's available. I do  
13 categorize it, so I am selecting -- I  
14 am identifying or analyzing the  
15 information for what it describes.  
16 And then if you go further on down, I  
17 try to tell you what I think is  
18 important about that information.

19 The overall conclusions I'm  
20 drawing in the report, though, when I  
21 cite to specific studies in the risk  
22 assessment, the majority of those  
23 studies I believe that I'm citing for  
24 you, outside of notice, have to do  
25 with -- that's more of a warnings

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1 issue -- have to do with the issue of  
2 cosmetic talc. Because the human  
3 studies are describing cosmetic talc.  
4 The NTP studies is a pure talc. Many  
5 of the in vitro studies and other  
6 animal studies are looking at,  
7 quote/unquote, a talc that is not an  
8 industrial grade or from a mine that  
9 would have -- be looked at in that  
10 way. So --

11 QUESTIONS BY MS. BRANSCOME:

12 Q. You understand that there are  
13 different types of cosmetic talc, correct?

14 A. Yes, I am aware.

15 Q. And cosmetic talc can be mined  
16 from a number of different mines globally,  
17 correct?

18 A. That's correct.

19 Q. And some of the studies that  
20 you cite in your report are testing cosmetic  
21 talc from other consumer products, for  
22 example, Cashmere Bouquet, correct?

23 A. Some. The majority of them are  
24 not, but I would agree that some do, yes.

25 Q. Okay. Have you done an

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1 analysis of how the talc that is used in  
2 Cashmere Bouquet, for example, relates to the  
3 talc that is used in Johnson's baby powder?

4 Is that an analysis that you  
5 have done before relying on that information  
6 in your report?

7 MR. MEADOWS: Objection.

8 MS. PARFITT: Objection.

9 THE WITNESS: My analysis -- I  
10 did do an analysis to look at what was  
11 described, what products are  
12 described, but I certainly -- I  
13 certainly did not throw out studies  
14 that described Cashmere Bouquet  
15 because I would -- I still believe as  
16 a toxicologist and a risk assessor  
17 that those types of products are  
18 important to the overall weight of the  
19 evidence about the hazard and the  
20 risks posed by talc.

21 You know, I just -- I just -- I  
22 guess I disagree with you if you're  
23 saying they're irrelevant. I don't  
24 believe that they are.

25

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.     I was simply asking: Did you  
3     do an analysis that would allow you to  
4     compare the ingredients in another product,  
5     like consumer Cashmere Bouquet, before you  
6     rendered an opinion with respect to Johnson's  
7     baby powder based on tests of Cashmere  
8     Bouquet? Did you do that analysis?

9           MR. MEADOWS: Objection.

10          THE WITNESS: I do not have  
11     access to internal company documents  
12     for the manufacturers of Cashmere  
13     Bouquet, so I certainly couldn't do  
14     the analysis in the same way that I  
15     can do it here, where I can identify  
16     what Johnson & Johnson and Imerys  
17     describe as sources of the talc that  
18     was used for the Johnson & Johnson  
19     baby powder, without --

20       QUESTIONS BY MS. BRANSCOME:

21           Q.     So you have no way of knowing  
22     one way or the other whether that talc is  
23     similar, correct?

24           MR. MEADOWS: Objection.

25           MS. PARFITT: Objection.

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1                   THE WITNESS: Well, I think I  
2                   do know it's similar, if you look on  
3                   the bottle as far as what is described  
4                   it being, but if you're asking me --  
5                   if you're asking did we fingerprint it  
6                   to only a particular mine, this is the  
7                   beauty of the data. The data shows  
8                   that regardless of the type of product  
9                   you're looking at, there's consistency  
10                  across the study.

11                  So -- but I did not try to  
12                  segregate out studies that only dealt  
13                  with Cashmere Bouquet, no, I did not  
14                  do that.

15                  QUESTIONS BY MS. BRANSCOME:

16                  Q.        Okay. As you sit here today as  
17                  a toxicologist, is it your position that  
18                  industrial-grade talc that might contain up  
19                  to 70 percent tremolite presents the same  
20                  level of toxic effect as cosmetic talc that  
21                  may contain no tremolite or tremolite at a  
22                  very, very low level?

23                  MS. PARFITT: Objection. Form.

24                  THE WITNESS: I haven't formed  
25                  that opinion, no.

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.        Okay. And so have you formed  
3       an opinion that I could find in your report  
4       that discusses in any way the relative  
5       toxicity of different types of talc?

6           A.        That, you may find. I need to  
7       go back and look how I set it out, but I  
8       think I -- I talked with you about the  
9       difference between fibrous versus platy. I  
10      do discuss that.

11                  And I talk about the problems  
12       when you have a complex mixture that has  
13       added to it things like asbestos and heavy  
14       metals, because I talk about the additivity  
15       issue that can come to play. So that -- in  
16       other words, increased risk when you have a  
17       complex mixture with additional components  
18       that all share the same toxic properties as  
19       far as target organs or types of effects or  
20       mechanisms that are triggered in the body.  
21      That's what I point you to.

22                  I -- I don't -- that's the only  
23       way I can answer that for you, I think, based  
24       on what I know I have in here.

25           Q.        Okay. You talk about the term

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1 "asbestiform talc."

2 You talk about asbestiform

3 talc.

4 Are you familiar with that?

5 A. I do mention that in my report,  
6 yes.

7 Where are you?

8 Q. At paragraph 30. It's on  
9 page 19 of your report.

10 A. Yes, I'm here.

11 Q. Okay. And the first sentence  
12 in paragraph 30 you state, "In the published  
13 medical literature, there is often discussion  
14 of talc using terms such as fibrous talc,  
15 asbestiform talc, non-asbestiform talc or  
16 tremolite."

17 Do you see that?

18 A. Yes, I do.

19 Q. Okay. Is it your opinion that  
20 tremolite is a form of talc?

21 A. So tremolite is a -- is a -- is  
22 a type of fiber or a -- tremolite is a -- is  
23 a substance or a entity that has been  
24 identified as a specific morphology, I guess,  
25 identified characteristics of a -- it has

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1 identified characteristics.

2 There's -- within the  
3 asbestos -- the asbestos literature  
4 there's -- it's one of the forms -- forms of  
5 asbestos that's described. For example, in  
6 IARC, they describe all of the ones that have  
7 carcinogenic properties. It's one of them.

8 Within the literature within  
9 Johnson & Johnson's documents, there's  
10 tremolite discussed as -- I assume them  
11 referring to asbestos tremolite, asbestos in  
12 a tremolite characteristic. I have seen  
13 tremolite talc also mentioned in the  
14 literature.

15 If you want a specific  
16 discussion of each of those, again,  
17 there's -- I understand there's experts that  
18 are going to describe the distinguishing  
19 characteristics of each of those.

20 I'm only setting out this is  
21 what I have seen, talked about, in the  
22 literature.

23 Q. So you are not an expert on the  
24 differences between fibrous talc, asbestiform  
25 talc, non-asbestiform talc and tremolite as

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1 it relates to toxicity. Is that your opinion  
2 today?

3 A. No, that's not what I'm saying.  
4 I'm saying that if you want me to -- I'm --  
5 if you want me to describe the  
6 characteristics and the morphology of each of  
7 those individually, that's something a  
8 geologist would do.

9 But certainly as far as the  
10 toxicity assessment I did, each of these  
11 types of -- each of these words, I guess, or  
12 names have been applied in the literature  
13 when they talk about toxicity of talc. Some  
14 of the literature talks about fibrous talc or  
15 just -- other literature just talks about  
16 talc. Some of it, for example, the IARC  
17 monographs, distinguish between asbestiform  
18 talc and non-asbestiform talc in their  
19 assessments of the cancer risk.

20 And then tremolite is discussed  
21 as a component of talc. And I have seen  
22 papers that talk about tremolite --  
23 nontremolite talc or tremolite-containing  
24 talc. That's how you most often see it.

25 So it's the idea that it is a

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1 constituent of certain mines that -- and  
2 that's my understanding of it. But if you  
3 want -- and they all -- they all certainly do  
4 show that the toxicity can be affected,  
5 whether it's a fiber or a platy particle. So  
6 tremolite being a fiber would certainly  
7 affect my overall assessment of risk. The  
8 more tremolite that you would have would  
9 make -- would make it more likely to be  
10 reactive in terms of a foreign body response,  
11 depending on the size.

12 Q. What's your basis for saying  
13 that?

14 A. That's based on a fibrous form  
15 versus a platy particle form. That's the  
16 issue of -- I have that paragraph where I  
17 talk about what macrophages look for, can  
18 engulf or not engulf. So those are all  
19 things that are important to a toxicologist  
20 to understand exist.

21 But certainly within my  
22 assessment I have to include literature from  
23 all of those because of the fact that all of  
24 those are relevant to the toxicity profile,  
25 since I know that the cosmetic baby powders

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1 and the data I've seen shows detection of  
2 something called fibrous talc.

3 I see detection of tremolite  
4 within certain samples of baby powder.

5 And then I have just the  
6 general category of asbestosiform versus  
7 non-asbestosiform when I consider the way, for  
8 example, IARC has reviewed the  
9 carcinogenicity.

10 So those are -- those are terms  
11 that I'm laying out because I think they are  
12 something you need to understand exists in  
13 the literature.

14 Q. Okay. But I'm trying to  
15 understand, not helping me understand the  
16 literature. I'm trying to understand your  
17 opinions with respect to toxicity.

18 Is it, for example, your  
19 opinion that fibrous talc has the same toxic  
20 potential -- let's focus specifically with  
21 respect to ovarian cancer -- as tremolite?

22 A. I haven't formed that opinion,  
23 but, again, I would -- my opinion has been  
24 formed on the fact that we have complex  
25 mixture that includes all of these things.

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1           Q.        Okay. And so when you're  
2 looking at a complex mixture, you would agree  
3 as a toxicologist it would be important to  
4 understand the constituent elements of that  
5 mixture, correct?

6           A.        Yes, it is important to  
7 understand that this is -- what is in the  
8 mixture, and that's -- that's part of what I  
9 try to do.

10          Q.        Okay. And it would be  
11 important before drawing conclusions from one  
12 study that might have different constituent  
13 components, it's important to understand the  
14 relative toxicity of individual constituent  
15 elements, correct?

16          A.        Depends if you can or not. I  
17 mean, there's certain types of studies you  
18 can, where in the published literature that's  
19 been described. That's why I'm pointing this  
20 out. It's the idea that within the  
21 literature, when you go through, it's  
22 important to understand what you can say  
23 about the consistency across the literature  
24 where maybe different types of talc are  
25 discussed.

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1                   And that's what I -- I think I  
2 lay out for you. I tell you there's  
3 consistency in certain toxic effects that are  
4 seen. Regardless of the form that you're  
5 looking at, talc has certain properties, and  
6 all of these things are -- been shown to be  
7 in the complex mixture, so I have -- as a  
8 result, all of that literature has relevance  
9 to at least the hazard part of my assessment,  
10 and certainly have relevance to -- when you  
11 want to talk about warning and the final risk  
12 assessment, they're definitely relevant, but  
13 certainly the -- when I go through this  
14 process, I am trying to focus as much as I  
15 can on a product that is most similar to the  
16 one I'm assessing.

17                   So obviously that's why --  
18 that's one of the reasons I do look at the  
19 human data, because the human data is  
20 involving a consumer product use, which is  
21 what I'm talking about here.

22                 Q.       Is it using specifically  
23 Johnson's baby powder?

24                 A.       Many of them are, yes.

25                 Q.       Okay.

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1           A.       Based on my understanding of  
2 what I see discussed within the literature.

3           Q.       Did you identify in your report  
4 specifically which report -- which studies  
5 have used a consumer product manufactured by  
6 Johnson & Johnson?

7           A.       I haven't laid them out  
8 individually, no, but I am aware of  
9 discussions of this general issue within some  
10 of the documents I've seen, and essentially  
11 Johnson's body powders products were the  
12 overwhelming share of the market.

13          Q.       But you would agree that  
14 studies that did not involve the consumer  
15 product manufactured by Johnson & Johnson  
16 should be given less weight when analyzing  
17 whether or not there are risks associated  
18 specifically with Johnson & Johnson's  
19 products?

20              MS. PARFITT: Objection. Form.

21              MR. MEADOWS: Objection.

22              THE WITNESS: It depends on the  
23 question being asked within the  
24 assessment, the risk assessment. It  
25 really does, I mean, because each of

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1           these studies brings a piece of  
2           evidence to the risk assessment.

3                 And so the question is -- for  
4           each one, you consider it on a  
5           case-by-case basis. It is possible,  
6           yes, that you would give less weight.  
7           It's also possible that you would not,  
8           dependent upon what you know about  
9           that study and how it relates to other  
10          studies that are out there.

11        QUESTIONS BY MS. BRANSCOME:

12           Q.       So methodologically, how would  
13          I understand from your report marked as  
14          Exhibit 4 under what circumstances to give a  
15          study that relates to, for example,  
16          industrial talc less weight than a study that  
17          actually used Johnson's baby powder?

18           MR. MEADOWS: Objection.

19           THE WITNESS: Well, I've tried  
20          to tell you that. That's what I said  
21          for you. That's why I am doing it. I  
22          certainly am trying to focus in on  
23          studies that deal with the consumer  
24          product.

25           But what I find when I look

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1                   across the studies that are dealing  
2                   with not the consumer product but  
3                   other descriptions, there is a  
4                   consistency in the types of effects  
5                   you see.

6                   And since I'm not quantifying  
7                   the risk but identifying it as being  
8                   increased or not, in other words, is  
9                   it more likely than not that someone  
10                  exposed in this way could be at a risk  
11                  of ovarian cancer, that's what I'm  
12                  talking about.

13                  So again, it's -- if I was  
14                  trying to identify differences in  
15                  cancer potency factors for different  
16                  types, then, yes, if I had an animal  
17                  study on each of those, I could  
18                  compare potency for cancer, but that  
19                  hasn't been done.

20                  QUESTIONS BY MS. BRANSCOME:

21                  Q.        Okay.

22                  A.        So instead, what I have to do  
23                  is rely on what is available to me. And  
24                  based on my judgment, that's how I review the  
25                  studies.

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1           Q.       And so for the opinions that  
2       you are offering in the MDL, you agree that  
3       you are not quantifying the risk associated  
4       with Johnson's baby powder, SHOWER TO SHOWER®  
5       or Shimmer with respect to the potential for  
6       causing ovarian cancer?

7                   MS. PARFITT: Objection. Form.

8                   THE WITNESS: In terms of a  
9       cancer potency factor, that is true, I  
10      am not. Instead, what I am doing is I  
11      am quantifying whether or not I  
12      believe that the risk is increased  
13      above a background risk.

14                  That has to do with -- that's  
15      where I bring in, in my risk  
16      assessment, the human data, because  
17      the human data is showing  
18      statistically significant increases in  
19      risk in populations using the consumer  
20      product.

21                  So I have a quantification  
22      where I'm using the word "increased,"  
23      and I believe to a reasonable degree  
24      of medical certainty that indeed the  
25      risk is increased. So I'm quantifying

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1           in that way, but I'm not giving it a  
2           number. I'm not saying that the  
3           cancer potency factor is such that you  
4           increase the risk from one in a  
5           million to 10 in a million to 1 in a  
6           thousand. That I have not done  
7           because I don't have the data, the  
8           studies. The company has not done  
9           studies on each of these to allow me  
10          to do that.

11          QUESTIONS BY MS. BRANSCOME:

12          Q.        Okay. The reference that you  
13          made to the human data that you believe shows  
14          a statistically increased risk in populations  
15          using the consumer product, have -- which --  
16          have you identified in your report which of  
17          those studies are specifically using a  
18          product that was manufactured by Johnson &  
19          Johnson?

20          A.        I don't lay that out for my  
21          report, I do not, but certainly it is  
22          something that for some of the studies I  
23          believe you can -- you might be able to get  
24          some of that information from. But certainly  
25          I have not laid that out individually in my

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1 report, no.

2 Q. And you would agree that for  
3 some of those studies there is no information  
4 as to the specific type of consumer talc that  
5 the individuals who are being studied used,  
6 correct?

7 MS. PARFITT: Objection. Form.

8 THE WITNESS: I would agree  
9 that in some of those studies they're  
10 not saying, but that is why you look  
11 at the evidence overall.

12 And what's important to look at  
13 in terms of now -- if you wanted to go  
14 to Bradford Hill, that's why you look  
15 at things such as consistency. So  
16 what do the studies show. We see a  
17 certain level of increased risk across  
18 studies, regardless of who did the  
19 study or what population was being  
20 looked at.

21 So that's the best way I can  
22 answer that for you. That is -- that  
23 is part of the -- of the assessment  
24 that you look at.

25

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.     In reaching your opinion in the  
3     MDL that there is an increased risk above  
4     background of ovarian cancer from the use of  
5     products manufactured by Johnson & Johnson,  
6     have you made an attempt to identify  
7     specifically which studies, the human studies  
8     on which you rely, test or look at people who  
9     have used Johnson & Johnson's products?

10           MS. PARFITT: Objection. Form.

11           THE WITNESS: It's my -- my  
12          review of the study indicates that I  
13          would say for the vast majority of  
14          them you cannot do that.

15           But you can take what is  
16          reported and look at things such as  
17          market share and those kind of things  
18          to get an idea of what you believe the  
19          exposure would have been.

20           But certainly I have not -- I  
21          have not tried to apply some kind of a  
22          numerical value to how many people in  
23          the study may have used Johnson's baby  
24          powder or not, no, that has not been  
25          done. I don't think anybody -- any of

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1           the bodies that have looked at this  
2           have done that.

3       QUESTIONS BY MS. BRANSCOME:

4           Q.       You have not done a market  
5       share analysis, correct?

6           A.       No, I've seen this in documents  
7       only. I have not done my own. There are  
8       company documents that talk about their  
9       market share.

10          Q.       Okay. Have you made an attempt  
11       to examine the levels of fibrous talc or  
12       asbestiform talc that are in different  
13       consumer products, aside from Johnson's baby  
14       powder or SHOWER TO SHOWER® or Shimmer?

15          A.       So for that are you referring  
16       to things such as -- other types of cosmetics  
17       like foundations or lipsticks or --

18          Q.       I'll rephrase.

19           Have you made any attempt to  
20       examine whether other cosmetic talc body  
21       powders have a different percentage of  
22       fibrous, or what you refer to as asbestiform  
23       talc, from the Johnson & Johnson products?

24           Have you done any analysis to  
25       make that comparison one way or the other?

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1 MS. PARFITT: Objection. Form.

2 THE WITNESS: I certainly

3 haven't done -- I certainly didn't do  
4 a directed analysis to try to  
5 determine that, but there is  
6 information, I believe, in -- I think  
7 if you look at some of Dr. Longo's  
8 work, that may be there.

9 And I believe in Dr. Blount's  
10 published paper there may be a  
11 discussion of the type of powder  
12 product used, where she was looking  
13 for -- at least for asbestosiform --  
14 asbestos within the talc. It may be  
15 tremolite as well, but -- if you want  
16 me to look, I can do that. I just  
17 don't recall whether -- I think she  
18 did talk about sources of the talc,  
19 where it came from, so...

20 QUESTIONS BY MS. BRANSCOME:

21 Q. Okay. But as you sit here  
22 today, you can't point me to any analysis  
23 that you did or an analysis that you relied  
24 on that would relate different brands of  
25 cosmetic talc body powders with respect to

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1       their constituent components?

2                                  MS. PARFITT: Objection.

3                                  Completely misstates her testimony.

4                                  She mentioned Dr. Blount. She  
5                                  mentioned others.

6                                  THE WITNESS: So I think what I  
7                                  started with, I said I haven't done a  
8                                  directed analysis to try to determine  
9                                  specifically how this product versus  
10                                 this product versus this product may  
11                                 have looked over time, because I don't  
12                                 have access to a full data to do that.

13                                 But what I do have is data that  
14                                 has -- I do see published data, for  
15                                 example, Blount and maybe some of the  
16                                 other published studies, that looked  
17                                 at this issue, at least of asbestos  
18                                 presence in talc. And I believe  
19                                 Dr. Longo also had things that weren't  
20                                 just Johnson's. I believe he had  
21                                 Cashmere Bouquet, for example, samples  
22                                 in some of the things he looked at.

23                                 So I can point you to those  
24                                 things that I have reviewed, but I  
25                                 haven't -- there's nowhere in here

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1           that I state for you that it's my  
2           opinion that Cashmere Bouquet has this  
3           specific pattern of constituents as  
4           compared to Johnson & Johnson's. No,  
5           I have not done that.

6        QUESTIONS BY MS. BRANSCOME:

7           Q.        Okay. And that would be true  
8        for any other brand of cosmetic talc, body  
9        powders, Jean Nate, Lily of the Valley, not  
10      just Cashmere Bouquet, correct?

11         MS. PARFITT: Objection.

12         THE WITNESS: That is correct,  
13         I don't have access to that  
14         information.

15        QUESTIONS BY MS. BRANSCOME:

16           Q.        Have you done any analysis of  
17        the constituent components of talc and how  
18        they have changed even within Johnson's --  
19        Johnson & Johnson's manufactured products,  
20        how the constituents of the consumer products  
21        may or may not have changed over time?

22           A.        I've done some of that, yes,  
23        and I laid that out, I think, for you, when I  
24        talk about the differences in the products  
25        that are described within the documents, the

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1 company documents, from the '70s versus the  
2 '80s versus later on, as far as the changes  
3 that were made to specifications of the  
4 product, for example. That's something --  
5 and I think I've talked about that a bit at  
6 trial as well.

7 Q. Okay. And is it your view that  
8 the risk potential for Johnson & Johnson's  
9 manufactured products have changed at all  
10 over time with respect to ovarian cancer?

11 MS. PARFITT: Objection.

12 THE WITNESS: I have not -- I  
13 have not attempted to differentiate a  
14 risk potential at only one point in  
15 time.

16 What I have done over points of  
17 time is looked at the issue of  
18 warnings and what should be warned  
19 about.

20 But my analysis related to the  
21 hazard or the risk assessment of the  
22 products is considering all of the  
23 available information, which would be  
24 all of that information over time.

25

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.        Okay. You talk about, in  
3 paragraph 35 primarily -- we'll talk about  
4 the fragrance components in more detail, but  
5 you talk about the idea of chemicals being a  
6 potential irritant.

7                   Are you familiar with that?

8           A.        Yes, that's correct.

9           Q.        Is it your position that any  
10 product that contains chemicals that could be  
11 an irritant should be labeled with a health  
12 warning?

13                  MS. PARFITT: Objection.

14                  MR. MEADOWS: Okay.

15                  THE WITNESS: I don't think  
16 that's -- no, I don't think I've  
17 formed that specific opinion.

18                  But the opinion that I think  
19 I'm expressing here is that when you  
20 have a -- the information that I have,  
21 which unfortunately the company hasn't  
22 given us percentages or actual levels,  
23 instead, what I do as a toxicologist,  
24 I look at what is there. And when I  
25 see over a hundred chemicals there,

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1           that 70 percent of them have been  
2           linked as an irritant hazard, there is  
3           the issue of toxicological additivity  
4           to consider.

5                 So certainly as a risk  
6           assessor, when I have that many  
7           potential sources of irritation as far  
8           as chemicals going into a complex  
9           mixture, certainly I think I have  
10          formed the opinion that I think that  
11          is something that needs to be  
12          considered when you're talking about  
13          providing information to consumers,  
14          yes.

15        QUESTIONS BY MS. BRANSCOME:

16           Q.       As a toxicologist, would it be  
17          important to you to understand the exact  
18          percentages of all of the constituent  
19          components of, say, Johnson's baby powder,  
20          for example?

21           A.       Are you talking about just the  
22          fragrance or are you talking about everything  
23          that's in it?

24           Q.       Dr. Plunkett, you referenced  
25          the fact that the company has not provided

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1 you with specific percentages, and so I'm  
2 asking you, is that something that as a  
3 toxicologist would be important information  
4 to you?

5 A. Depends. Certainly with the  
6 fragrance -- and I'm talking about the  
7 conversation about this paragraph is focusing  
8 on the fragrance components.

9 So, yes, I mention that it  
10 would be nice to know, it would be good to  
11 know, if we could, exactly what was in there,  
12 because I could quantify the hazard or  
13 quantify the risk, actually. So instead, I  
14 have -- I identify it as a hazard, but I  
15 can't quantify it without those levels.

16 But does that change -- make a  
17 difference in the overall conclusions I draw?  
18 No, it doesn't affect the overall conclusions  
19 that I have drawn, but it adds that other  
20 piece of the puzzle that deals with the fact  
21 that we have a complex mixture that have a  
22 combination of ingredients that target  
23 irritation.

24 And irritation and the  
25 potential to produce an inflammatory

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1 response, in my -- if you've read my report,  
2 you understand that I think that's a key  
3 factor in increasing the risk for ovarian  
4 cancer.

5 Q. Understanding the percentages  
6 of the constituent components, is that  
7 limited only to fragrance, or would it also  
8 be important to understand the percentages  
9 for the heavy metals that you contend are in  
10 Johnson's baby powder?

11 A. So if I was trying to define  
12 the hazard of each component, I would  
13 certainly want one to know that. As a  
14 result, what I'm doing instead is looking at  
15 the complex mixture. In other words, this is  
16 a mixture of all these things.

17 I break out those individual  
18 components, or constituents, to tell you  
19 about the hazard that is brought to play or  
20 the toxicity profiles that exists. And  
21 what's important about that in my overall  
22 evaluation of the end product, which is what  
23 my risk assessment is based on, the end  
24 product, shows that I have multiple  
25 components with similar types of effects.

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1 And as a toxicologist, when you do that, that  
2 affects the conclusion that you can draw  
3 about a body of literature.

4 Q. Okay. You do understand that  
5 there is testing data available about the  
6 percentages of the constituent components  
7 with respect to heavy metals, et cetera, that  
8 have been in Johnson's baby powder over time,  
9 correct?

10 A. There is some information.  
11 Unfortunately, the information is not  
12 complete as to every lot or every sample, as  
13 far as what I have seen. And also, there's  
14 some -- some of the sampling is reported as  
15 more of a limit versus an actual  
16 quantification. So it depends upon which --  
17 which result, study result or document,  
18 you're looking at.

19 There is some there, yes, and  
20 that's one of the reasons why I identified  
21 these as part of my risk assessment, because  
22 I look for a pattern of these metals that are  
23 known to carry a hazard and whether or not  
24 these are ones I'm seeing detected time and  
25 time again.

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1           Q.       But you made no attempt to  
2 quantify the risk with respect to any of  
3 those components or use that data in any way,  
4 correct?

5                     MS. PARFITT: Objection. Form.

6                     THE WITNESS: No, I used  
7                     that -- that data as part of -- my  
8                     risk assessment as part of my hazard  
9                     assessment, absolutely. It's part of  
10                   the hazard assessment.

11                  But as far as quantifying them  
12                  individually, no. I am quantifying  
13                  the risk and looking at the risk of  
14                  the entire product, not of just one  
15                  individual component of the product.

16                  QUESTIONS BY MS. BRANSCOME:

17            Q.       Well, we already discussed  
18            you're not quantifying the risk with respect  
19            to the entire product, correct?

20           A.       Well, I'm quantifying it in  
21            terms of an increase above background, which  
22            I'm not giving you a -- I told you I wasn't  
23            giving you a cancer potency factor. That is  
24           true. That I am not doing.

25                  But I am quantifying it by

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1       using a word such as an increase -- an  
2       increased risk.

3                             Is that a specific number? Am  
4       I telling you that it's increased by two  
5       times or four times or six times? No. The  
6       data available did not allow us to do that,  
7       with the exception of the epidemiological  
8       data. And the epidemiological data can show  
9       you that in that piece of evidence there  
10      appears to be a 30 percent increased risk  
11      above background.

12                          Q.       Did you make an attempt to  
13      quantify the risk with the data that you had  
14      available to you with respect to the final  
15      consumer product?

16                          A.       I could not, based on the data  
17      I had, because I didn't have a  
18      well-controlled animal study to be able to  
19      pull that out that way.

20                          Instead, what I -- in this type  
21      of weight of the evidence, you look at what  
22      you might be able to quantify based on the  
23      human data. And certainly the human data  
24      showing the statistically significant  
25      consistent findings across studies for that

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1       30 percent increased risk, that is part of my  
2 overall weight of the evidence for me making  
3 the statement the risk is increased.

4                     But you'll notice I don't say  
5 increased risk of 30 percent, because I don't  
6 believe that I can state that with certainty  
7 in the way I do a risk assessment. But  
8 certainly as any one individual -- any one  
9 individual piece of evidence or any one body,  
10 like the epi data, others have made -- other  
11 bodies who have looked at the -- talked about  
12 the consistency of the increased risk signal  
13 in the epi studies as being in the range of  
14 30 percent.

15               Q.        Okay. But you would agree that  
16 based on the methodology that you applied in  
17 this case, you could not say to a reasonable  
18 degree of scientific certainty that there is  
19 an increased risk of, for example, 30 percent  
20 with respect to use of Johnson's baby powder  
21 and ovarian cancer, correct?

22                     MR. MEADOWS: Objection.

23                     THE WITNESS: I have not done  
24 that. And I'm not saying that  
25 somebody else couldn't do that. I

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1 have not -- I have not chosen to do  
2 that based on my evaluation of the  
3 data.

4 QUESTIONS BY MS. BRANSCOME:

5 Q. And the same would be true if I  
6 asked that question and substituted any  
7 particular number, a 10 percent increased  
8 risk, a 20 percent increased risk, correct?

9 MR. MEADOWS: Objection.

10 THE WITNESS: I haven't given a  
11 specific number in my final opinions,  
12 that is true.

13 QUESTIONS BY MS. BRANSCOME:

14 Q. Okay.

15 A. I've tried to explain to you  
16 what evidence I do think is there, however.

17 Q. Now, we've talked about  
18 different types of talc that might have  
19 different constituent components, but you  
20 also look at exposure to talc in an  
21 occupational setting.

22 Do you recall that?

23 A. Some of the studies that I've  
24 relied upon, yes, some of them were  
25 occupational.

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1                   Q.         Okay. And you understand that  
2     in an occupational setting, you would agree  
3     that the exposure, particularly via  
4     inhalation, would be much higher than it  
5     would be through the use of a consumer  
6     product, correct?

7                   A.         It depends on the occupation,  
8     but, yes. For example, I would agree a miner  
9     would be expected to have that, but there are  
10    certain, quote/unquote, occupational studies  
11    where the exposure levels that -- for  
12    example, there are -- I believe there's at  
13    least one study that looked at application of  
14    talc powders in -- maybe in a material,  
15    coating materials in a factory. Those kinds  
16    of studies would be different than a mining  
17    study.

18                  But, certainly, yes, I  
19    understand that occupational studies, the  
20    inhalation exposure is the pathway that would  
21    be predominant versus in the consumer body  
22    powder use, I'm talking about the predominant  
23    exposure pathway in my opinion is going to be  
24    through perineal use, even though inhalation  
25    exposure can occur.

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1           Q.       Is it your opinion as you sit  
2 here today that someone could develop ovarian  
3 cancer through -- exclusively through the  
4 inhalation of Johnson's baby powder?

5           MS. PARFITT: Objection.

6           THE WITNESS: I haven't formed  
7 that opinion at this point in time.

8 QUESTIONS BY MS. BRANSCOME:

9           Q.       Have you done any analysis or  
10 can you point me to any analysis in your  
11 report that makes a comparison of the  
12 exposure levels that might be seen in an  
13 occupational setting to what would be seen by  
14 a consumer?

15          A.       Are you asking me for a piece  
16 of evidence that does that comparison, or is  
17 there evidence that allows you to do that  
18 comparison?

19          Q.       Have you cited or discussed any  
20 of the evidence or done an analysis in any  
21 way that would compare exposure levels in an  
22 occupational setting to what you would  
23 anticipate a consumer using Johnson's baby  
24 powder might be exposed to?

25          A.       I don't think I did it as a

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1 separate analysis, but as part of my analysis  
2 I considered evidence that showed -- provided  
3 me with such data. So, for example, if you  
4 want, I can point you to a -- I have an  
5 inhalation paragraph, I think.

6 Let me look for it real quick.  
7 See if I can find it quickly for you. I  
8 don't want to waste your time.

9 Q. Sure.

10 A. So there's -- I don't see it  
11 cited here, but there's at least one document  
12 I reviewed where the company themselves made  
13 a comparison, and I have seen that, of  
14 inhalation exposure to talc suspended in air  
15 with diapering. Dr. Longo has done a  
16 measurement of exposure in air with perineal  
17 application of talc. So I'm aware of those  
18 studies.

19 And then I certainly am aware  
20 of the fact that those numbers are different,  
21 or smaller, than many of the numbers I see  
22 reported in some of the occupational studies.  
23 But I can't say that's true for all.

24 I would certainly, though, say  
25 that if you're just talking inhalation, I

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1 certainly would expect a miner or a miller to  
2 have a greater potential for inhalation  
3 exposure than routine use of the consumer  
4 product, with the exception of the studies --  
5 the reports of large amounts of exposure in  
6 children where the inhalation -- where they  
7 were inhaling large amounts of powder.

8                   And so that's a different  
9 story. That's sort of an acute overdose  
10 exposure, I guess, versus the typical daily  
11 exposure through occupational or consumer  
12 use.

13               Q. And that raises an interesting  
14 question. You discuss health hazards  
15 associated with talc being known, and in some  
16 cases deaths had been reported.

17                   You're aware that those relate  
18 to asphyxiation deaths, correct?

19               A. Or long-term injury to lungs.  
20 Maybe not an immediate asphyxiation, but lung  
21 damage produced by large amounts -- some of  
22 the children would go to the hospital and be  
23 sick for a while and then die. So they  
24 didn't asphyxiate immediately, right? But  
25 some of them did. You're exactly right.

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1                   Both of those things occur, and  
2 I address that also in my warning section  
3 about the fact that that warning didn't --  
4 was not put on the product for a long period  
5 of time even though those types of reports  
6 were coming in early.

7                 Q.     You would agree that that is a  
8 completely different biologic mechanism than  
9 what you are proposing the biological  
10 mechanism is for ovarian cancer to develop  
11 with respect to talc use, correct?

12                 MR. MEADOWS: Objection.

13                 THE WITNESS: I would agree  
14 that it's an acute response versus  
15 chronic, yes, that I agree with.

16                 It's not entirely different in  
17 some cases because some of the tissue  
18 reactions you saw were indicative of  
19 irritation when some of the lung  
20 samples were looked at. But  
21 certainly, yes, that's acute exposure  
22 versus chronic exposure, and I'm  
23 focusing on ovarian cancer on chronic  
24 exposure scenarios.

25

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.        Okay. Now, you would agree

3       that -- so let's set aside inhalation.

4                   You agree that for talc -- for  
5       Johnson's baby powder or another one of  
6       Johnson & Johnson's consumer talc products to  
7       reach an individual's ovaries, it must pass  
8       from the perineum, through the vagina and the  
9       cervical canal, move across the uterus -- and  
10      again, it's the ciliary motion of the  
11      fallopian tubes -- cross the peritoneal space  
12      between the fimbriae and ovaries, escape  
13      phagocytosis in the peritoneal space, and  
14      then attach to the surface of the ovaries,  
15      correct?

16                  MS. PARFITT: Objection. Form.

17                  MR. MEADOWS: Okay.

18                  THE WITNESS: If the issue is  
19       attaching to the surface, yes.

20       There's also some information  
21       indicates the site of attack may be  
22       actually at the fallopian tube exit to  
23       the peritoneum. But, yes, that's  
24       correct, there's been some discussion  
25       in the literature on ovarian cancer

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1           about whether the tumors are arising  
2           in the tubes versus the ovaries.

3                 But I would agree, I think  
4                 both -- I think both of those  
5                 things -- those things -- there is a  
6                 passage that has to happen, regardless  
7                 of whether the end point is at the  
8                 fallopian tube or at the ovary.

9     QUESTIONS BY MS. BRANSCOME:

10           Q.        Okay. Is it your view that the  
11           consensus has been reached that ovarian  
12           cancer can be caused by talc landing in the  
13           fallopian tubes?

14           A.        I haven't formed that opinion,  
15           though I do believe this will be discussed by  
16           some of the other experts.

17           Q.        Okay. Have you personally  
18           conducted any tests or experiments to confirm  
19           the theory that talc migrates from  
20           application at the perineum to the ovaries?

21           A.        If by that you mean something  
22           where I performed a laboratory test myself,  
23           no, I have not done that.

24           Q.        As a toxicologist, are you  
25           capable of doing that?

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1           A.       Yes, I believe if asked I  
2       could -- I could attempt to design something  
3       to look at that issue.

4           Q.       Okay.

5           A.       But I would argue that I think  
6       it doesn't make a lot of sense to revisit  
7       based upon what we already know from the  
8       scientific literature and the review papers  
9       from the gynecological community. I believe  
10      it's -- it's understood that it can migrate.

11          Q.       In your opinion, has an animal  
12       model been successfully developed that would  
13       allow the testing of talc migration in humans  
14       from the perineum to the ovaries?

15          A.       I think I tell that you in my  
16       report. I believe that the human data is the  
17       relevant data to look at this issue.

18                 So it would be very difficult  
19       to design a study to do this based on the  
20       typical laboratory species that are used in  
21       toxicology testing. Even -- even the monkeys  
22       have issues, and the biggest issues with  
23       monkeys is the ethicality of using a monkey  
24       to settle -- to address a question that I  
25       believe is settled within the gynecological

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1 and scientific community.

2 Q. Now, you state in your report  
3 that talc that's applied through perineal  
4 use -- I believe the term you use --  
5 routinely migrates to the ovaries.

6 Is that your opinion?

7 A. Are you reading from my report?

8 MR. MEADOWS: To the extent  
9 that question is still lingering, I  
10 object to it.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. On paragraph 43 on page 29.

13 A. So I think as I've stated it,  
14 the studies that I have reviewed demonstrate  
15 that inert particles routinely move from the  
16 lower female reproductive tract up into  
17 fallopian tubes and towards the ovaries.

18 Q. What do you mean by routinely?

19 A. It's the percentages of  
20 movement that are reported in the patients.  
21 In other words, if you look at some of the  
22 individual studies -- if you want we can pull  
23 them out, but, you know, eight of ten  
24 patients, nine of ten patients, all the  
25 patients showed movement of the particles.

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1                   And then on top of that, you  
2 have the review articles that talk about  
3 migration of particles in the female  
4 reproductive tract and are describing it as  
5 an event that is known to occur. So it's  
6 those things weighed together.

7                   But certainly routine could be  
8 supported by the observations where the  
9 majority of the patients in the studies were  
10 showing movement of inert particles.

11                  Q.       Is it your opinion that every  
12 perineal application of cosmetic talc powder  
13 results in talc being deposited on the  
14 ovaries?

15                  A.       I have not formed that opinion,  
16 no.

17                  Q.       Have you formed an opinion as  
18 to with what frequency -- so let's say  
19 someone uses a cosmetic talc on a perineal  
20 application ten times. Out of those ten  
21 times, have you formed an opinion as to how  
22 many of those instances would talc deposit on  
23 the ovaries?

24                  MS. PARFITT: Objection.

25                  THE WITNESS: I haven't formed

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1           an opinion in that particular way, no.  
2           I think what I've -- I've tried to  
3           describe to you in my report is that I  
4           believe it is known that inert  
5           particles have the ability to migrate.  
6           And based on that, I form the opinion  
7           that it's my opinion to a reasonable  
8           degree of scientific certainty, which  
9           would be a more likely than not  
10           standard, that particles of talc would  
11           be migrating when women are using them  
12           perineally. But I haven't told you  
13           that it has to be a specific number,  
14           no.

15          QUESTIONS BY MS. BRANSCOME:

16          Q.       Have you done any analysis to  
17          establish over a lifetime use of cosmetic  
18          talc where the app -- the perineal  
19          application, with what frequency during a  
20          lifetime the talc may have been deposited on  
21          that individual's ovaries?

22          A.       So I certainly looked for  
23          information to allow me to assess that, but  
24          unfortunately those kinds of studies would be  
25          unethical to do. Because that would be a

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1 matter of sampling women during -- using them  
2 and then taking biopsies, and that's  
3 something that would be difficult to do. I  
4 would say impossible to get approval to do  
5 under human testing guidelines.

6 Q. Okay. So it's your opinion  
7 that it is possible for talc that is applied  
8 through a perineal application to reach the  
9 ovaries, but you cannot say with what  
10 frequency that occurs?

11 MS. PARFITT: Objection. Form.  
12 Misstates her testimony.

13 THE WITNESS: That's not --  
14 what I'm telling you is, I think it --  
15 that to a reasonable degree of  
16 scientific certainty that it migrates,  
17 and that would be the standard of more  
18 likely than not. I think it's more  
19 likely than not that the talc is  
20 reaching the ovaries when people are  
21 using it perineally.

22 I did form the opinion -- and  
23 I've talked about this at trial and  
24 yesterday. I have formed the opinion  
25 that this is a issue of chronic or --

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1           or use of the products. In other  
2           words, people aren't just using it  
3           once, but people are using it -- you  
4           can use the word "routinely," as a  
5           habit, in their daily life perineally.  
6           And that would be consistent with the  
7           studies that have been done that have  
8           looked at the issue of dose response.

9                 And I discuss that in my  
10          report, too.

11        QUESTIONS BY MS. BRANSCOME:

12           Q.        Okay. But you have not made an  
13           attempt to quantify, nor have you seen it in  
14           the literature, the overall dose of talc that  
15           someone might be exposed to in terms of  
16           contact with the ovaries throughout their  
17           lifetime, chronic use of cosmetic talc?

18                 MS. PARFITT: Objection. Form.

19                 THE WITNESS: Those -- that's  
20                 the kinds of studies that have not  
21                 been done and I believe could not be  
22                 done based upon ethics of human  
23                 testing. But certainly I -- that --  
24                 that data is not available that I'm  
25                 aware of.

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1 MS. BRANSCOME: Okay. Can we  
2 just go off the record for a second?

3 VIDEOGRAPHER: We are going off  
4 the record at 12:23 p.m.

5 (Off the record at 12:23 p.m.)

6 VIDEOGRAPHER: We are back on  
7 the record at 12:24 p.m.

8 QUESTIONS BY MS. BRANSCOME:

9 Q. As you sit here today, how  
10 would you characterize the biological  
11 mechanism by which you claim Johnson's baby  
12 powder, their other cosmetic talc products,  
13 present a risk of ovarian cancer?

14 A. So I outline this for you in  
15 the MDL report. I think I have a section  
16 on -- let's see if I can -- you want me to  
17 tell you where or...

18 So paragraph 65, I think I set  
19 out part of this argument or part of this.  
20 And then also in paragraph -- I believe in  
21 67.

22 Q. All right. Well, let me take a  
23 step back.

24 Is it your opinion that the  
25 biological mechanism by which talc, cosmetic

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1 talc, can in your view cause ovarian cancer,  
2 is that something that has been definitively  
3 established?

4 A. What do you mean by  
5 definitively? I mean, I think -- I believe  
6 more likely than not that -- so I believe I  
7 have reached a conclusion that I think what  
8 the most likely biologically plausible  
9 mechanism, but maybe you're ask -- meaning  
10 something else.

11 Q. Okay. Well, let's start with  
12 specifically you discuss a number of  
13 different potential mechanisms in your  
14 report. So if you believe you have reached  
15 an opinion more likely than not about the  
16 specific biological mechanism by which  
17 cosmetic talc and specifically Johnson &  
18 Johnson's products can cause ovarian cancer,  
19 can you describe that for me?

20 A. So it's a chronic inflammatory  
21 process, and so -- but like all compounds,  
22 constituents, even drugs that we look at, we  
23 don't know each individual step within the  
24 molecular mechanism.

25 Instead, what we know is that

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1 there are certain components to the process  
2 of cancer that are consistent with the  
3 effects produced by talc, and we know that  
4 talc can produce a chronic inflammatory  
5 process.

6 And so that's why I was  
7 pointing you to the paragraph 65 and I think  
8 67.

9 Q. Is it your opinion that  
10 consensus has been reached in the scientific  
11 community that cosmetic talc can cause  
12 ovarian cancer through a chronic inflammatory  
13 response?

14 MS. PARFITT: Objection.

15 THE WITNESS: I don't know that  
16 that's exactly the opinion I've  
17 formed.

18 Would you like me to -- I could  
19 restate what I believe, but I don't  
20 think that's exactly how I would state  
21 it, no.

22 QUESTIONS BY MS. BRANSCOME:

23 Q. Okay. So then yes or no: Has  
24 consensus been reached in the scientific  
25 community that cosmetic talc can cause

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1 ovarian cancer through a chronic inflammatory  
2 process?

3 A. I don't believe I formed the  
4 opinion either way, that it's yes or no,  
5 because I haven't tried to -- I haven't tried  
6 to form the opinion about what the -- in  
7 other words, I haven't -- I can't say for  
8 every scientist out there.

9 I certainly can tell you what I  
10 believe based on what the consensus of  
11 science says about mechanisms underlying  
12 cancer and the consistency of those  
13 mechanisms with talc, and then I have an  
14 opinion about what I believe that information  
15 says.

16 I do believe my opinions,  
17 however, are consistent with some consensus  
18 statements, such as the issue on the  
19 mechanism is consistent with consensus  
20 opinion reached by IARC, where they discuss  
21 the inflammatory process as an underlying  
22 biologically plausible mechanism that can  
23 lead to ovarian cancer.

24 I think it's consistent with  
25 the Canadian risk assessment where they

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1 discuss those issues.

2 I think it's consistent with --

3 I don't know if the ACOG statement goes that  
4 far on mechanism, but it does talk about  
5 ovarian cancer. That's a recent statement.

6 And I believe it's consistent  
7 with some of the -- I believe my opinions are  
8 consistent with some of the opinions reached  
9 by others in science, but that's the only way  
10 I can answer that for you.

11 Q. Okay. Because you have not,  
12 one way or the other, done an evaluation of  
13 whether or not chronic inflammatory process  
14 is a biological mechanism on which the  
15 scientific community has reached general  
16 consensus with respect to the causation of  
17 ovarian cancer; is that correct?

18 MR. MEADOWS: Objection.

19 THE WITNESS: I can't tell you  
20 that -- I can't tell you that every  
21 body that's looked at it, but I have  
22 tried to point you to evidence that I  
23 believe is consistent with that.

24 For example, the IARC would be  
25 a good example of consensus on

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1           biologic mechanism because they have a  
2           whole part of their assessment of  
3           non-asbestiform talc and perineal  
4           cancer -- of perineal use and ovarian  
5           cancer that discusses mechanism. And  
6           that is consistent with what I have  
7           said. So there is a consensus  
8           opinion.

9           But I guess what I'm saying to  
10          you is I can't tell you that all --  
11          all people who have put statements  
12          have come to that exact opinion. But  
13          there aren't that many places out  
14          there that are addressing that issue  
15          as far as the consensus on a  
16          mechanism. There's more statements  
17          about the relationship between ovarian  
18          cancer and talc use than there are  
19          drilling down to what the mechanism  
20          must be.

21          QUESTIONS BY MS. BRANSCOME:

22          Q.        Okay.

23          A.        So that's the issue. It's a  
24          little -- it's a little hard to answer that  
25          yes or no because of that.

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1                   Q.         Okay. When we talk about the  
2 idea of biologic -- a biologically plausible  
3 mechanism, what is your understanding of the  
4 term "plausible" in that expression?

5                   A.         When I use the word  
6 "biologically plausible mechanism" or  
7 "biologic plausibility," I'm using it  
8 consistent with what Bradford Hill uses,  
9 that's it's the idea that the evidence that  
10 available makes -- the evidence that  
11 available supports a pathway where you can go  
12 to exposure to response.

13                   So in other words, there's a --  
14 the biological information is consistent with  
15 how we know cancer can develop. That's the  
16 response we're looking at. And the exposure  
17 we're looking at is known to produce those  
18 kind of biologic events.

19                   So as a result, based upon  
20 knowing that there's a consistency between  
21 the data that we have on the -- on the  
22 exposure and the data that we have on the way  
23 cancer can occur, those things -- those  
24 things align. So that makes it biologically  
25 plausible that that could occur.

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1           Q.       But you would agree that  
2     biological plausibility suggests that it is a  
3     plausible explanation, but it may not have  
4     been established as the definitive pathway by  
5     which a disease is caused, correct?

6           MS. PARFITT: Objection. Form.

7           THE WITNESS: Well, I would  
8     agree that in the discussion of  
9     biologic plausibility in the Bradford  
10   Hill paper that is true. But if you  
11   look at people's discussion of the use  
12   of -- I want to say "biological  
13   mechanism" rather than the word  
14   "biologic plausibility," because  
15   really as a toxicologist I'm trying to  
16   understand whether there's a biologic  
17   mechanism that makes sense. Those are  
18   words I like to use. Does it make  
19   sense that this exposure could lead to  
20   this response.

21           And that involved looking at  
22   the mechanistic data or the data on  
23   the way toxic responses are produced  
24   by talc, and whether or not they align  
25   with the types of toxic insults that

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1           are known to be able to produce,  
2           specifically, ovarian cancer.

3       QUESTIONS BY MS. BRANSCOME:

4           Q.       Is it your opinion that IARC,  
5       for example, has concluded that the  
6       biological mechanism by which talc may cause  
7       ovarian cancer is chronic inflammation?

8           MS. PARFITT: Objection.

9           THE WITNESS: I don't know that  
10       they have used -- they've described it  
11       quite that way, but they do describe  
12       what they believe is the biologically  
13       plausible mechanism. Because they do  
14       organize and use within the  
15       definitions of how they describe some  
16       things that are consistent with what  
17       Bradford Hill uses.

18       QUESTIONS BY MS. BRANSCOME:

19           Q.       Okay. And obviously you're  
20       familiar with the IARC evaluation of talc  
21       with respect to the possibility of causing  
22       ovarian cancer, correct?

23           A.       Yeah. If you mean the recent  
24       one, yes, the most recent assessment.

25           Q.       Yes.

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1                   And that IARC has in fact  
2 classified cosmetic talc not containing  
3 asbestos as possibly carcinogenic to humans,  
4 correct?

5                   A.       It's a possible human  
6 carcinogen 2B, that's correct.

7                   Q.       Okay. And if a product is  
8 listed in the 2B category, does that  
9 necessarily mean the product, in your view,  
10 is carcinogenic?

11                  A.       Not always, because that comes  
12 down to an assessment of -- then you're  
13 putting together a -- a risk assessment that  
14 looks at -- looks at -- across the  
15 information that you have available. And  
16 that may be that -- that the -- the possible  
17 is all you can say, or it may be that you  
18 believe that the information -- there's  
19 enough information there to take it further.

20                  Has a possibility -- that's  
21 what I said, they do a hazard assessment.  
22 They rank things on hazard based on -- on  
23 unlikely -- not enough evidence, less -- the  
24 possibility, the probability or it's known.

25                  Q.       In your opinion, is your

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1 characterization of the risk of Johnson's  
2 baby powder or talcum powder products with  
3 respect to ovarian cancer, are you in the MDL  
4 characterizing that risk as a higher level of  
5 risk than what IARC characterized it, or do  
6 you agree with the 2B characterization of  
7 possibly carcinogenic?

8 MS. PARFITT: Objection. Form.

9 THE WITNESS: So I'm not IARC,  
10 so I don't try to second-guess there.  
11 They have reached a conclusion, and I  
12 use that as part of my weight of the  
13 evidence. So I haven't formed the  
14 opinion they're right or wrong.

15 But I have done a different  
16 assessment. My assessment, first off,  
17 includes more information than IARC  
18 had, so as a result, I have formed the  
19 conclusion that I believe that it's  
20 more likely than not that exposure  
21 to -- perineal exposure to talc body  
22 powders increases the risk of ovarian  
23 cancer in women who use that product.

24 And I will put the caveat this  
25 has to be chronic use or repeated use,

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1 because I've gone -- I've said that  
2 many times.

3 So that -- that is my opinion.

4 So that's a different statement and a  
5 different assessment than what IARC  
6 does.

7 But -- so I don't disagree with  
8 their possible -- I weigh that, but I  
9 believe the evidence for the risk  
10 assessment shows me that it's more  
11 likely than not that this -- this  
12 exposure will increase the risk above  
13 a background risk for women who are  
14 using this product.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. And how do you define chronic  
17 or repeated use?

18 A. Well, that is variable within  
19 the literature. For me, chronic is  
20 exposure -- if as a toxicologist, I would  
21 typically say chronic use is years of use.  
22 It doesn't have to be daily, but it would be  
23 years. That's the most common description  
24 you see in toxicology, so I would say that's  
25 fair. That's a fair assessment of my

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1       opinion.

2           Q.       Is there a threshold of the use  
3       of Johnson & Johnson's talcum powder products  
4       below which there is no increased risk, in  
5       your opinion, of ovarian cancer?

6           A.       We have not identified that  
7       threshold. That's what's missing within  
8       the -- the literature that exists today. So  
9       I can't tell you whether or not with only a  
10      thousand applications over a lifetime that  
11      is -- is not enough for every individual or  
12      not, but certainly I do believe that the --  
13      that the exposure has to be habit, routine,  
14      chronic, something that is done maybe not on  
15      a daily basis but on a routine basis in a  
16      woman's life.

17                  So that is consistent, I think,  
18       with the literature.

19                  MS. BRANSCOME: Okay. We can  
20       go off the record.

21                  VIDEOGRAPHER: We are going off  
22       the record at 12:36 p.m.

23                  (Off the record at 12:36 p.m.)

24                  VIDEOGRAPHER: We are back on  
25       the record at 1:35 p.m.

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.       Good afternoon again,

3       Dr. Plunkett.

4           A.       Good afternoon.

5           Q.       I want to talk a little bit  
6       about the Health Canada assessment.

7                   We talked about this before,  
8       but this is something that you reviewed after  
9       you completed your report which has been  
10      marked as Exhibit 4, correct?

11          A.       Yes, and I wanted to tell you,  
12      I did not bring all those documents printed.  
13      I apologize. So there is a separate Health  
14      Canada draft risk assessment that I didn't  
15      print.

16          Q.       Okay. So when you're referring  
17      to the Health Canada analysis, what document  
18      are you specifically referring to?

19          A.       So I'm referring to the -- the  
20      combined documents, but there are times when  
21      you've asked me questions that I've been  
22      referring -- and I tried to say, I believe,  
23      Taher.

24                   But, yes, some of the questions  
25      you asked me when I said Health Canada, I was

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1 talking about the combined documents, which  
2 would include their -- I guess it's called a  
3 draft risk assessment document, yeah, which  
4 refers to this document but is a separate --  
5 is their own separate statement.

6 Q. As you sit here today, what is  
7 your understanding of the current position  
8 that has been articulated in the collection  
9 of documents that you refer to as Health  
10 Canada with respect to any potential  
11 relationship between cosmetic talc and  
12 ovarian cancer?

13 A. So that's why I did print out  
14 the small one, because I think it summarized  
15 it. So here, if you look at this Exhibit 6,  
16 it makes specific conclusions or draws --  
17 makes statements. And essentially it talks  
18 about talc being a possible risk of ovarian  
19 cancer, but then it gives women specific  
20 advice about what to do in order to minimize  
21 exposure to the products, and some of that  
22 was relevant as well.

23 Just one reason I printed it  
24 out, it has to do with either choosing an  
25 alternative product or avoiding genital

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1 exposure to talc.

2 And let me see the exact words

3 that they use, but --

4 Q. Before you do that, do you  
5 agree with the characterization that cosmetic  
6 talc presents a possible risk of ovarian  
7 cancer?

8 A. No, I don't think that's my  
9 opinion. I think my opinion is stronger than  
10 that.

11 But are you talking about my  
12 causation analysis opinion or just my risk  
13 assessment opinion?

14 Q. I'm asking about any opinion  
15 you intend to offer in the MDL.

16 A. Okay. So I will not be giving  
17 the causation analysis opinion, so that -- I  
18 will take that off the table.

19 So I think my opinion is a  
20 little stronger because I say that the  
21 exposure to the perineal -- the talc by  
22 perineal application in women increases the  
23 risk. So I'm not saying it's a possible  
24 risk. I'm actually -- I believe that it  
25 increases the risk. And I do believe that

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1 there is a association between those two  
2 things, the exposure and the response, which  
3 is more than a possible association, if you  
4 want to use those words.

5 But my assessment that I've  
6 done is not exactly the same, for example, as  
7 IARC does, which is more of just a hazard  
8 assessment.

9 Q. Right.

10 So I'm focusing my questions  
11 now on your risk assessment as compared to  
12 the documents that you've supplied us with  
13 with respect to Health Canada. And if I  
14 understand it correctly, are you stating that  
15 your opinion with respect to the relationship  
16 between cosmetic talc and ovarian cancer, you  
17 believe that it is an association that is  
18 stronger than a possible risk; is that  
19 correct?

20 A. Well, I don't say it's a  
21 possible risk; I say there is an increased  
22 risk. So I think it's a different statement,  
23 yes, absolutely.

24 Of course, I'm not Health  
25 Canada, so, you know, they have a framework

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1       upon which they make decisions, and I'm doing  
2       an analysis based on what I have done. And  
3       so it's not exactly the same, although some  
4       of the same documents and information is  
5       weighed within -- and then that's when you  
6       have the issue of what Health Canada does  
7       versus what they rely upon.

8                   But this Taher risk assessment  
9       is just one piece of information that Health  
10      Canada has weighed in their assessment if you  
11      read their -- their draft risk assessment.

12       Q.       So the question I have about  
13      the Taher risk assessment, earlier you were  
14      referring to the fact that you have only seen  
15      a quantitative assessment of the weight of  
16      particular components of scientific evidence  
17      in evaluating epidemiological studies; is  
18      that correct?

19       A.       So that's what I typically see,  
20      yes. And I don't know that -- I've never  
21      seen it. But the typical approach would be  
22      to use it there as opposed to using it in the  
23      context of a human health risk assessment  
24      based on animal in vitro data.

25       Q.       All right. Are you familiar

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1 with something called the Klimisch scoring  
2 system?

3 A. I don't know if I am now.

4 You'll need to show me what it is you're  
5 referring to. The name doesn't ring a bell,  
6 no.

7 Q. Okay. So it's not something  
8 that you've used in the past?

9 A. No, not that I recall using.

10 Q. All right.

11 A. Unless it has another name, and  
12 that's why I'm asking you.

13 Q. All right. So if you have  
14 actually -- it's the document in front of you  
15 that we've already marked as Deposition  
16 Exhibit 5, I believe.

17 A. Yes.

18 Q. And that is the Taher study  
19 that we were discussing and is cited by the  
20 Health Canada risk assessment.

21 If you turn to page 5 -- well,  
22 actually beginning on page 4, do you see  
23 there is a section entitled "Literature  
24 Search and Identification of Relevant  
25 Nonhuman Studies"?

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1                   Do you see that?

2                   A.       Yes.

3                   Q.       And this is related to an  
4                   analysis that these authors performed on  
5                   potentially relevant animal and in vitro  
6                   studies, correct?

7                   A.       Yes, that is true.

8                   Q.       All right. And it states here  
9                   that "all retrieved studies were examined for  
10                  relevance, reliability and overall quality  
11                  using the Klimisch scoring system."

12                  Do you see that?

13                  A.       Yes, I do see that. So I have  
14                  seen that before. I just didn't -- I didn't  
15                  recall it.

16                  Q.       Okay. And so would you agree  
17                  that it is possible and in fact has been done  
18                  in a study that you rely on to apply a  
19                  quantitative scoring system to animal and in  
20                  vitro studies, particularly in the context of  
21                  looking at the relationship between talc and  
22                  ovarian cancer?

23                  A.       Well, I didn't say it was  
24                  impossible. I said I don't believe it's  
25                  routine based on my experience.

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1                   So, yes, if they stated they've  
2 done -- we'd have to pull the supplementary  
3 materials out, but I recall them doing  
4 scoring based on epi studies but not on  
5 the -- all of the animal studies that they  
6 talk about. But we can pull it out and look.  
7 I could be wrong.

8                   Q.        Okay. Did you review the  
9 supplementary material 7, 8 and 9?

10                  A.        Yes, I did, and we'd have to  
11 pull them out because I don't recall the  
12 details.

13                  Q.        All right. We may take a look  
14 at those in a minute.

15                  It talks about them classifying  
16 the animal and in vitro studies into four  
17 categories of reliability.

18                  Do you see that?

19                  A.        Yes.

20                  Q.        So did you make any attempt,  
21 when you were reviewing the various studies  
22 in reaching your opinion about the potential  
23 risk of talc in causing ovarian cancer, did  
24 you make any attempt to separate out the  
25 different pieces of evidence into categories

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1 of reliability like the authors of this paper  
2 have done?

3 A. I didn't do it exactly the way  
4 they did it, but I certainly do do that as  
5 part of my screening.

6 I told you one of the  
7 characteristics or one of the assessments I  
8 make is whether I believe the data is  
9 reliable data that I can -- that I can use in  
10 a weight of the evidence. So I make a -- and  
11 when I talk about reliability, I'm talking  
12 then about things such as I mentioned, peer  
13 review, whether or not there is statistical  
14 analysis, whether or not the study is  
15 designed in a way that's consistent with  
16 general principles of toxicology, control  
17 groups or not control groups.

18 Those kinds of things I do -- I  
19 do consider when I am assessing the use of a  
20 study or not.

21 Q. Is it your testimony here today  
22 that contained within your report that's  
23 marked as Exhibit 4, I could find  
24 categorization of reliability of each of the  
25 pieces of scientific literature that you have

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1 included in your weight of the evidence  
2 analysis? Is that your testimony today?

3 A. No, that's not what I'm telling  
4 you, no.

5 Q. Okay. So you would agree that  
6 you did not -- first of all, did you develop  
7 categories of reliability in which you  
8 separated the particular scientific studies  
9 into as part of your weight of the evidence  
10 analysis?

11 A. I do look at -- I do categorize  
12 studies based upon my assessment of their  
13 reliability and their ability to be used to  
14 answer the question I'm asking, but I -- I  
15 already told you, I didn't do it the way it's  
16 set out here. I didn't have these specific  
17 five categories, no. That's not what I did.

18 Q. Okay. Other than the CIR 2013  
19 publication, which you have said that you do  
20 not find reliable and you assign little  
21 weight to it, can you point me to another  
22 place in Exhibit 4 where you assign a  
23 specific category of weight that you have  
24 given to a particular study that you include  
25 in your weight of the evidence analysis?

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1                   A.         If what you're asking me is do  
2 I make a specific statement next to each  
3 study that I discuss about little weight or  
4 great weight, no, I don't do that, if that's  
5 what you're asking me.

6 Q. Okay. As part of the  
7 collection of documents that relate to Health  
8 Canada that was provided to us as part of  
9 your new reliance list, did you review a  
10 document entitled weight of the evidence --  
11 or "Weight of evidence: General principles  
12 and current applications of Health Canada"?

13 A. Yes, I've seen that.

14 (Plunkett Exhibit 8 marked for  
15 identification.)

16 QUESTIONS BY MS. BRANSCOME:

17 Q. All right. We will mark this  
18 as Plunkett Deposition Exhibit Number 8.

19 All right. The document that I  
20 just handed you that's marked as Plunkett  
21 Deposition Exhibit Number 8, are you familiar  
22 with that document, Dr. Plunkett?

23 A. Yep, I've seen this before.

24 Q. Is this listed among the new  
25 materials that have been added to your

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1 reliance list?

2 A. I believe it was, yes.

3 Q. Okay. And so for this one I  
4 just want to direct your attention to the  
5 conclusion section -- well, let me ask you  
6 first: How does this document relate to the  
7 collection of documents with respect to  
8 Health Canada that you identified as relevant  
9 to your opinion?

10 A. It was one of the materials  
11 that they rely upon or they cite. That's the  
12 reason I pulled it. It was -- I pulled  
13 documents that they provided on the website  
14 that were cited.

15 Q. Okay. And if you could turn to  
16 page 11 of that document, there's a  
17 conclusion section. The first sentence of  
18 the third paragraph reads, "The given --  
19 given the context-specific nature of each  
20 risk assessment and the diversity of tools  
21 and criteria applicable, transparent  
22 documentation of the specific application of  
23 the WOE approach is especially important."

24 Did I read that correctly?

25 A. Yes, you did.

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1           Q.       And is your understanding of  
2 WOE that it is weight of evidence?

3           A.       Yes, that's correct.

4           Q.       Do you agree with this  
5 statement?

6           A.       In a regulatory context, I do  
7 believe that that is true, because within the  
8 regulatory context when they do the risk  
9 assessment, there's a need to understand why  
10 decisions are made. So, absolutely, in a  
11 regulatory context, I would agree that this  
12 kind of transparency is even being adopted by  
13 EPA.

14          Q.       And is it your opinion then  
15 that a different level of transparency is  
16 needed for expert testimony in court?

17          A.       No, that's not what I'm saying.  
18 I'm saying that's a different process. And  
19 that's what part of this process is. It's  
20 understanding the ability to provide a dialog  
21 about what was done.

22                   So as a result, this is  
23 something that is common to the work that  
24 I've done in the past. Even in a  
25 nonlitigation context with my regulatory

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1 clients, doing a risk assessment doesn't  
2 necessarily involve the same level of detail  
3 that a regulatory -- a regulator would apply  
4 to the transparency of the assessment. Not  
5 to say that it couldn't be done, but it's  
6 just -- I would say it's not necessarily  
7 typical.

8 Q. So this specifically refers to  
9 transparent documentation.

10 A. Do you see that?

11 Q. Yes.

12 Q. Would you agree that the report  
13 that you have produced in the MDL does not  
14 have documentation of the specific  
15 application of the weight of evidence  
16 approach?

17 MS. PARFITT: Objection.

18 Excuse me, objection. Form.

19 THE WITNESS: I disagree to an  
20 extent because I did attempt to  
21 provide in my report a description of  
22 the methods that I used and the  
23 resources that I've relied upon for a  
24 discussion of how those methods are  
25 used.

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1                   And then in addition to that,  
2                   I've attempted to lay out for you in  
3                   my report a discussion of the pieces  
4                   of evidence that I've relied upon,  
5                   including some -- for some of those --  
6                   that's one of the reasons I got so  
7                   detailed in the section on migration  
8                   and providing you an analysis of each  
9                   of the papers that I relied upon and  
10                  what I thought was important within  
11                  them that led to my -- the formation  
12                  of my opinions.

13                   So I disagree to some extent.

14                  QUESTIONS BY MS. BRANSCOME:

15                  Q.        Okay. Turning back to what  
16                  Taher did in classifying different studies  
17                  into different categories of reliability.  
18                  Have you done that type of analysis in the  
19                  past where you have separated out different  
20                  studies into different categories of weight  
21                  or reliability as part of an overall  
22                  analysis?

23                  A.        Well, I do that every time I do  
24                  a weight of the evidence when I separate into  
25                  categories first based upon the type of

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1 study. In other words, as I discussed many  
2 times in deposition, when you're talking  
3 about doing a human health risk assessment,  
4 there's certain types of data that are most  
5 relevant. I mean, when they use the word  
6 "reliable" -- I don't know that many of these  
7 studies have the same level of reliability as  
8 far as peer review, but they're -- for  
9 example, on the issue of migration, it's my  
10 opinion that the data from the human studies  
11 is a more reliable or relevant source of  
12 information. And I've laid out why, because  
13 of differences in the anatomy, things like  
14 that, with the data.

15 Q. Are you familiar with the term  
16 "binning exercise"?

17 A. Yes, I am. And that is  
18 certainly something that I have used in other  
19 aspects of work that I have done.

20 Q. Did you do a binning exercise  
21 in rendering your opinions and what you've  
22 provided to us in the context of your  
23 opinions in the MDL?

24 A. Yes, that's the exercise I  
25 start with. I'm binning them into human,

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1 animal, mechanistic, in vitro data. That's  
2 the first bins.

3 In fact, in the copper work we  
4 did, that's what we did. We separated the  
5 data into in vitro/only mechanistic  
6 information, animal studies, did we have  
7 human studies.

8 And we also looked at  
9 studies -- we had a separate bin of exposures  
10 like I do. I have studies that just address  
11 the issue of exposure potentially.

12 So, yes, it's -- it's  
13 consistent with doing that. It's --  
14 essentially binning is just separating the  
15 information into groups based on what  
16 questions those -- those data can answer.

17 Q. Okay. Have you ever -- do you  
18 ever separate them into bins based on the  
19 level of weight that you would give a  
20 particular study?

21 A. I do that when I'm analyzing  
22 each of the studies within that group or that  
23 bin. That's what I do. I give them -- in my  
24 weight -- in my analysis, I weigh those  
25 studies based upon my judgment on the

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1 relevance, the reliability, the power of the  
2 study, the statistical analysis that's done,  
3 the inclusion in animal studies, in  
4 particular, of controls. Those are all parts  
5 of that analysis that I do. So, yes, I do do  
6 that.

7 And then in -- there have been  
8 exercises that I've done in the past with  
9 other individuals where we may have taken a  
10 yellow sticky note and put down on top of it  
11 animal data with exposure information, animal  
12 data without exposure information. That's  
13 the process that I'm doing when I am looking  
14 across the data. I'm separating those pieces  
15 of data into groups and what types of  
16 questions they can answer.

17 So that is consistent with what  
18 I do when I do a weight of analysis approach  
19 in the work that I do in both nonlitigation  
20 and litigation context.

21 Q. Okay. But we have no specific  
22 documentation of the different ratings that  
23 you gave the various pieces of evidence that  
24 you included in your weight of the evidence  
25 analysis, aside from occasional references to

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1 giving something less or more weight,  
2 correct?

3 A. Well, I certainly -- I told you  
4 I have not given numerical values that you're  
5 asking me, but I've attempted to do that when  
6 I have described them in groups, when I talk  
7 about human versus animal versus in vitro.  
8 Because I've already told you, I believe,  
9 it's my opinion that certain types of  
10 information are more informative than others.  
11 And so the more informative it is, the more  
12 weight you're giving it in -- obviously in  
13 your analysis.

14 But it is a different exercise  
15 than what is described here. And here I'm  
16 pointing to Exhibit 8. And it's a different  
17 exercise, obviously, than what a regulatory  
18 body is required to do where they are trying  
19 to come up with ways to increase the  
20 transparency when no one can go and actually  
21 talk to each of the regulators individually  
22 to understand what their thinking was.

23 Q. Okay. Returning to biological  
24 mechanism for a minute, why doesn't  
25 inflammation generally, including chronic

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1       inflammation, cause ovarian cancer?

2           A.       Because it doesn't change the  
3       phenotype of the cell. It has to -- the --  
4       and I discuss that. You have to -- you have  
5       to set up a chronic inflammatory process that  
6       leads to changes within the cellular  
7       phenotype to go from a cell that is -- that  
8       is -- is dividing normally to a cell that  
9       isn't.

10              So it's -- it's the same issue  
11       that you address even in a study in animals.  
12       Why do not all animals exposed to -- exposed  
13       to a chemical develop tumors. It's the idea  
14       that something has to be initiated beyond the  
15       exposure or maybe beyond inflammation to lead  
16       to the series of events.

17              And so, yes, it's recognized  
18       that you can get inflammation, and  
19       inflammation can go down the road in becoming  
20       a carcinogenic process, or inflammation can  
21       no longer -- can stay where it is. It  
22       doesn't progress beyond just a chronic  
23       inflammatory process.

24           Q.       And so if you had a study that  
25       demonstrated that a particular agent causes

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1 inflammation, you would need more information  
2 in order to make the conclusion that that  
3 agent can in fact cause cancer, correct?

4 MR. MEADOWS: Objection.

5 THE WITNESS: You would look  
6 for more informative information,  
7 exactly, which is why, when I've  
8 talked about the individual  
9 constituents in the context of  
10 consistency on mechanism for cancer,  
11 I've pointed to documents where that  
12 information has been discussed.

13 So like when I talk about  
14 asbestos or cobalt or I point to  
15 the -- for example, the IARC  
16 assessment where they go through  
17 that -- that discussion of the fact  
18 that there's not just data showing  
19 that a biologically plausible  
20 mechanism may be inflammation, but  
21 there's also data to show that that  
22 can lead to tumor development as well.

23 QUESTIONS BY MS. BRANSCOME:

24 Q. Okay. How does talc change the  
25 phenotype of the ovarian cell?

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1                   A.         So this is one of the details  
2 we don't know, other than generally it's  
3 changing the phenotype to go from a normal  
4 cell to a tumor cell. That is being  
5 observed. When you find the presence of the  
6 tumor, that is what you're observing.

7                   Q.         Does pure talc with no other  
8 constituent components, can it change the  
9 phenotype of an ovarian cell?

10                  MR. MEADOWS: Objection.

11                  THE WITNESS: So that's a  
12 difficult question to answer with  
13 certainty because of the fact that I  
14 don't believe that we have assurance  
15 that any of the studies are done with  
16 essentially pure talc.

17                  However, in the studies that  
18 claim to have been done with pure  
19 talc -- for example, the NTP study  
20 claims to have been done with pure  
21 talc. So if that is pure talc, truly  
22 is, then that study is an example of  
23 evidence for the chronic inflammatory  
24 process leading to preneoplastic  
25 lesions that are setting down the road

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1 mechanism towards cancer.

2 So there are data out there.

3 The problem you have, I believe, in  
4 the literature is whether or not,  
5 based on the discussion that is  
6 becoming apparent now with sensitivity  
7 and ability to take the natural  
8 product and actually determine exactly  
9 what's in it, that I don't think there  
10 is the ability to assure that any --  
11 any of these studies with the samples  
12 of talc they're using is absolutely,  
13 100 percent, only platy talc. I think  
14 there's -- there's some concern about  
15 that. But certainly you will take --  
16 you have to take what is discussed  
17 within the study as evidence from what  
18 they're claiming.

19 So many of the studies say we  
20 used asbestos-free talc or platy --  
21 pure platy talc and we got a toxic  
22 response.

23 QUESTIONS BY MS. BRANSCOME:

24 Q. Would it be possible to design  
25 an experiment -- and now I'm talking about an

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1      in vitro or an animal experiment -- by which  
2      you would expose either cells or animal to  
3      talc with different constituent products to  
4      identify or separate out the individual  
5      effects of the components? Is that a study  
6      that you could design as a toxicologist?

7            A.       I think that would be difficult  
8      to do, but I'm not saying impossible to do.  
9      And here's the -- there are some very  
10     specific considerations you'd have to put  
11     into that design.

12            I would argue that some of that  
13     is already available, where we have studies  
14     that have looked at the dose-response effects  
15     for toxicity with cobalt, with chromium, with  
16     asbestos.

17            When you get to asbestos and  
18     talc, it's more problematic because then the  
19     question is what is -- what is it? What are  
20     the specific characteristics in all the  
21     different studies of exactly what the  
22     asbestos was versus exactly what the talc  
23     was.

24            But I think you could attempt  
25     to do that, and then the question would be,

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1 being able to use that data not so much to --  
2 not so much to identify a dose response for a  
3 certain insult, but to look at the fact --  
4 look at potency differences across the  
5 compounds. And then there's the issue of  
6 then looking at additivity when you know you  
7 have a complex mixture.

8 So that could be done, but,  
9 again, it would be difficult to do based on  
10 what we know about talc, being able to really  
11 know that -- you would have to really be very  
12 careful that what it is that you're looking  
13 at is -- is not containing any of those  
14 things that we unfortunately know co-occur  
15 with constituents within the natural product.

16 But no one has done those  
17 studies. I point that out. I haven't seen  
18 that study that you're asking for. I have  
19 not seen somebody do that.

20 Q. And a study like that would be  
21 relevant in evaluating the potency of the  
22 individual constituents and what might  
23 actually be the driving factor for phenotypic  
24 change, correct?

25 A. Not necessarily. I would argue

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1 that we already have an answer to that by  
2 looking at the data that's been collected on  
3 the complex mixture itself. So the issue  
4 would be why -- the question is what do you  
5 gain by being able to say that we're only  
6 pointing to this constituent or that  
7 constituent. That isn't what is occurring.

8 What people are exposed to is  
9 the complex mixture, not just each one of  
10 those individual components. To me this is  
11 not a case of asbestos-only exposure. This  
12 is a case of exposure to consumer products  
13 that are talc that may have within them at  
14 any given time -- and data indicates that  
15 there are substantial chance that asbestos  
16 may be in -- is in certain of these products.

17 But my opinions are not  
18 dependent on there being asbestos there at a  
19 particular level or copper there -- or, I'm  
20 sorry, cobalt there at a particular level  
21 because my opinions are based on the  
22 observations we have on the complex product  
23 as it exists.

24 Q. And you recognize that  
25 different types of talc and different talc

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1 products have different constituent  
2 components in different amounts, correct?

3 A. Some can. I agree with that.

4 That is true.

5 So if you're being broad, as in  
6 pharmaceutical-grade versus industrial-grade  
7 or chemical-grade, yeah, because they'll have  
8 a purity level assigned.

9 But as far as what the -- what  
10 the components are, it isn't always defined  
11 even specifically within that.

12 Q. Okay. And does the presence of  
13 oxidative stress in a tissue indicate that  
14 cancer will develop in that tissue?

15 A. Will definitively develop?

16 Not -- I don't think you could say  
17 definitively develop, but it's certainly in  
18 the biologically plausible mechanism that's  
19 been understood to lead to chronic  
20 inflammation and also has been linked to  
21 cancer.

22 So that's the issue of not  
23 necessarily saying it has to be there, but it  
24 certainly is something that is observed  
25 routinely in cases where carcinogenesis has

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1 been linked to an inflammatory response.

2 Oxidative stress is often a triggering  
3 mechanism.

4 Q. Does the body have protective  
5 mechanisms that limit tissue damage from  
6 oxidative stress?

7 A. Yes, which is why not everybody  
8 that's exposed to any particular chemical is  
9 going to get cancer. Some people will  
10 respond better. Some cells will respond  
11 better. Some individuals in a population at  
12 one time in their life may respond better.

13 Q. You would agree that in vitro  
14 studies do not account for the body's natural  
15 defenses outside of what exists at the  
16 cellular level, correct?

17 A. Depends on the in vitro study  
18 that's being done and whether or not there is  
19 components added.

20 So I've seen studies done where  
21 they take cells and then add extra levels of  
22 glutathione to try to protect the cells from  
23 certain stressors that could lead to damage,  
24 but I agree with you that an isolated cell on  
25 its own is a different microenvironment than

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1       an intact tissue, which is a different  
2       environment than an intact animal, which is  
3       even different than an intact human being.  
4       Yes, they're all -- you look at those levels  
5       of evidence or those types of evidence  
6       differently, depending upon the end points  
7       you're collecting.

8           Q.       And so you would give lower  
9       weight to an in vitro study as compared to an  
10      in vivo study, for example?

11          A.       Depends on the question you're  
12       asking. I would give a lot of weight if the  
13       question is what do I know -- if I want to  
14       try to understand the biologically plausible  
15       mechanism, some of those in vitro studies are  
16       some of the most important, because it's the  
17       only ones that allow us to answer a question.

18               If the question is higher level  
19       about what is the evidence to show that  
20       there's an increased risk overall for cancer  
21       or a hazard for cancer, then certainly you  
22       need to have more than an in vitro study.

23               So as -- so on -- if you want  
24       to layer it up, obviously, if all you had was  
25       in vitro data, you'd have much less

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1 confidence in the conclusions you can draw  
2 unless you had some in vivo data. In vivo  
3 data is going to allow you to interpret the  
4 in vitro data.

5 So certainly there would be  
6 more weight given in that assessment to the  
7 fact that you had in vivo data.

8 Q. And so when you made the  
9 statement that, for instance, you always give  
10 more weight to human data, is that true, or  
11 does that also depend?

12 A. Well, it depends on whether you  
13 have human data. So if I have human data and  
14 I have a doubt, any doubts at all, about  
15 whether or not the exposure-response  
16 relationship would be affected by the way the  
17 animal studies are designed, then, yes, I  
18 would give more weight to the human studies.

19 In a case, however, such as  
20 inhalation exposure assessments where  
21 there -- it's much better, actually, to do an  
22 animal study where we can do a dose response  
23 across different sizes of particles and  
24 actually observe lesions as they develop over  
25 time, which is why I love -- I love the NTP

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1       93 study of interim sacrifices, looking at  
2       that issue. That data is very reliable in  
3       order to understand the risk of lung damage  
4       as compared to a human study where we don't  
5       have those serial time points, doses that are  
6       defined tightly.

7                   So -- and the relevance between  
8       those kinds of initial lung injury in certain  
9       animals versus humans match fairly well.

10                  That's my problem, though, in  
11       the case with the perineal exposure. I'm  
12       saying to you, because of the route of  
13       contact -- we need to be able to get it there  
14       to the tissue -- the human data is extremely  
15       important.

16                  Q.       So is it fair to say that in  
17       some circumstances animal data gets more  
18       weight than human data and in other  
19       circumstances human data gets more weight  
20       than animal data? It is circumstance  
21       dependent?

22                  A.       I would put it a different way.  
23       I would say in some cases animal data is  
24       weighted in a similar manner to human data.  
25       I don't necessarily say it would get more

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1 weight, but it could if you only had one  
2 crappy human study, one really badly designed  
3 human study, and I had a GLP quality cancer  
4 bioassay then, absolutely. I mean, IARC does  
5 this. They look at that animal data and say,  
6 "This one tells us -- answers the questions  
7 we want to answer, and this very poorly  
8 designed case series isn't going to allow us  
9 to do that."

10 So you could, but I would say  
11 it's more the other issue, that you look at  
12 animal and human more on an equal basis if  
13 the relevance and the extrapolation can be  
14 done reliably.

15 And that's the question you  
16 have to ask, can I extrapolate from animals  
17 to humans in a reliable manner.

18 Q. Okay. Would you agree that the  
19 response to cosmetic talc can vary depending  
20 on tissue type in the body?

21 A. Yes, I would say that that is  
22 true, whether or not there's certain  
23 protective barriers in place, for example,  
24 yes.

25 Q. And so in order to draw

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1 conclusions based on a study of one cell  
2 type's reaction to cosmetic talc to another,  
3 you would need to understand the differences  
4 in similarities between those two cell types,  
5 correct?

6 MS. PARFITT: Objection.

7 THE WITNESS: It's a different  
8 question. So you were asking me  
9 about -- I didn't think you were just  
10 asking about cells. I thought you  
11 were asking me about like routes of  
12 exposure, dermal versus inhalation.  
13 Those things differ.

14 Cell types may or may not.

15 That may or may not be true. Because  
16 if two cells -- two different cell  
17 types in the body share similar  
18 characteristics as far as the -- for  
19 example, if they're both epithelial  
20 cells or mesothelial cells, those type  
21 of cells you would expect to respond  
22 the same way.

23 But I would agree that, for  
24 example, a neuronal cell versus a GI  
25 cell versus a liver cell, there could

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1           be differences in how they would  
2           respond, yes, and so you would -- you  
3           would look at those things  
4           individually.

5       QUESTIONS BY MS. BRANSCOME:

6           Q.       And so it's important to  
7           understand the differences and the  
8           similarities between the different cell types  
9           before drawing conclusions using studies from  
10          different cell types?

11           MS. PARFITT: Objection.

12           MR. MEADOWS: Objection.

13           THE WITNESS: I certainly think  
14          you should consider the cell types  
15          that are being used and whether or not  
16          those cell types are ones that are  
17          relevant to your risk assessment  
18          question you're asking, yes.

19       QUESTIONS BY MS. BRANSCOME:

20           Q.       Okay. You would agree as a  
21          toxicologist, dose is an important part of a  
22          toxicological analysis of an agent, correct?

23           A.       If you're doing risk, yes. If  
24          you're only doing hazard, it may not be as  
25          important. It depends upon the question

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1 you're asking about hazard.

2 Do you want me to explain?

3 Q. I do want you to explain the  
4 difference between a risk analysis and a  
5 hazard analysis.

6 A. Okay. So in an initial hazard  
7 analysis, if the question is, is there a  
8 hazard associated with exposure, let's say,  
9 by inhalation, it may not matter whether it  
10 was a high dose or a low dose study. Both of  
11 those can identify hazard.

12 Then you ask the question: Is  
13 there a dose-response relationship? That's  
14 the next step beyond hazard.

15 So hazard is -- to me is  
16 identifying the end points that you're going  
17 to monitor for toxicity, sort of the target  
18 organs, those things, and so whether or not  
19 there's a dose-response study available, it  
20 wouldn't be as important.

21 But certainly when you go to  
22 that next step to assess risk, you'd like to  
23 be able to see whether or not there is a  
24 dose-response relationship in the effect that  
25 you're assessing.

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1           Q.        Okay. And in your -- in your  
2 report, as part of your risk assessment that  
3 you did in the MDL -- this is paragraph 12 on  
4 page 8.

5           A.        Yes, I'm there.

6           Q.        Okay. You state about  
7 two-thirds of the way down the paragraph that  
8 "weight of the evidence methods were critical  
9 to defining the literature that identified  
10 the hazards of talc exposure as well as  
11 defining the dose-response relationship  
12 between talc exposure and the risk of adverse  
13 health effects."

14              Did I read that correctly?

15           A.        You did. That's correct.

16           Q.        All right. Is it your view  
17 that in the case you have reached an opinion  
18 that defines the dose-response relationship  
19 between talc exposure and the risk of ovarian  
20 cancer?

21           A.        It depends what you mean by  
22 define. I can tell you what I mean in this  
23 sentence, and maybe that would help you.

24           Q.        Dr. Plunkett, it is your  
25 report. And so I am asking you, using your

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1 own definition of "define," have you rendered  
2 an opinion that defines the dose-response  
3 relationship between talc exposure and the  
4 risk of ovarian cancer?

5 A. I have formed opinions about  
6 the dose-response relationship generally, but  
7 unfortunately -- I answered that question for  
8 you earlier when you asked me, I think, about  
9 is there -- I don't know if you used the word  
10 "threshold," but I did.

11 So the available information  
12 doesn't allow us to identify an ultimate  
13 threshold, for example, in the case of women  
14 exposed to talc perineally and their -- and  
15 their development of ovarian cancer.

16 Instead, in defining the dose  
17 response, what we can do with the data -- and  
18 that is what I attempted to do. This is  
19 where you look at defining the dose response  
20 in the animal studies, which we can look at,  
21 or defining dose response in cell studies,  
22 showing that as the dose increases, the  
23 hazard and the risk increase. So risk  
24 actually you quantify. There's a certain  
25 response at this dose and a different

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1 response at the next dose, or have we  
2 plateaued, that the responses are the same as  
3 dose increases.

4 So that, I did do that as part  
5 of my assessment, trying to define the dose  
6 as far as how that linked to the responses in  
7 each of the studies I looked at.

8 Q. You would agree, though, that  
9 some studies did not show a dose relationship  
10 between talc and ovarian cancer or the  
11 clinical signs that were indicative of the  
12 potential for development into ovarian  
13 cancer, correct?

14 MS. PARFITT: Objection.

15 THE WITNESS: If you're talking  
16 about the human data; is that what  
17 you're referring to? Or are you  
18 talking about all -- any of the data?

19 QUESTIONS BY MS. BRANSCOME:

20 Q. Any of the data.

21 A. So I would disagree on the  
22 animal data. I think on the animal data they  
23 often -- most of the animal studies I've  
24 relied upon have looked at more than one dose  
25 or at least looked a no exposure versus a

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1 dose, and most of them have looked at more  
2 than one dose.

3                   In the case of the human  
4 studies, unfortunately, some of those studies  
5 were not designed to be able to define dose.  
6 In other words, the questions weren't asked,  
7 for example, of the individuals even in the  
8 prospective studies. Some of those  
9 included -- did not include the information  
10 collected on frequency and duration of use.

11                  So if it's not collected,  
12 obviously, I don't have it to look at. And  
13 that's one of the limitations of human  
14 epidemiological investigations, is that it  
15 often is not designed appropriately to look  
16 at dose response.

17                  Q. Is it your opinion that there  
18 are no studies looking at talc and the risk  
19 of ovarian cancer in which the authors of the  
20 study have concluded there was no clear  
21 pattern of increased risk with dose?

22                  MS. PARFITT: Objection.

23                  THE WITNESS: No, that's not  
24 what I've said. No. It's very  
25 possible that an individual paper

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1           or -- that they may make a -- an  
2           author may make a statement, but I'm  
3           talking about looking -- this is  
4           weight of the evidence. I'm looking  
5           across. And I'm saying, across the  
6           data, when I look at the human data  
7           versus the animal data, for example,  
8           versus in vitro studies, the in vitro  
9           studies and the animal studies allow  
10          you to look at dose response for talc  
11          toxicity.

12           The -- even the animal studies  
13          allow you to look at dose response for  
14          development of precancerous lesions,  
15          you're on the way to cancer, for  
16          example, in the NTP studies.

17           And then in the human studies,  
18          some of those studies are designed  
19          such that the authors could draw  
20          conclusions about dose response and  
21          some are not.

22           Even in some of the studies  
23          where they attempted to look at dose  
24          response, some of the authors indicate  
25          they don't see an effect. So that is

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1           true. And part of that may be driven  
2           by the design of the study, the number  
3           of individuals in the study, the way  
4           that the questions were asked.

5           There's limitations on the way that  
6           information is collected.

7           If you want to look at each  
8           study, we can, but --

9           QUESTIONS BY MS. BRANSCOME:

10          Q.       So my question to you, whether  
11          you agree or disagree with the author's  
12          conclusion, is simply that if you look at the  
13          overall animal and human studies that you  
14          cite in your report or have considered on  
15          your reliance list that look at a potential  
16          dose-response relationship for talc toxicity,  
17          do some of those studies conclude that there  
18          is not a dose-response relationship?

19          MS. PARFITT: Objection.

20          THE WITNESS: I disagree for  
21          talc toxicity, but I would say if  
22          you're going to limit it to the issue  
23          of the ovarian cancer response, I  
24          would agree. I have seen that in some  
25          of the studies.

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1                   I think talc toxicity, I don't  
2                   know if anybody has made the  
3                   comment -- I would doubt it -- that  
4                   there is no dose response for toxic  
5                   effects of talc.

6        QUESTIONS BY MS. BRANSCOME:

7                   Q.        Okay. You discuss in your  
8 report -- wait a moment. It's in  
9 paragraph 58 on page 38. And I just want to  
10 make sure I understood what you were citing  
11 here.

12                  In paragraph 58 you state that  
13 "It is important to remember that  
14 administration of even a single dose of talc  
15 in animals has been shown to produce adverse  
16 effects locally at the site of the exposure."

17                  What are you referring to  
18 there?

19                  A.        Acute doses. In other words,  
20 in studies that have described installation  
21 of a single dose of talc in some form into a  
22 tissue, that they are observing adverse  
23 responses.

24                  An example of that may be  
25 the -- I think it's Hamilton. Is that the

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1 one where they stilled it into the ovaries  
2 with a single dose?

3 Q. So these are large-dose  
4 exposures?

5 A. Well, not all --

6 Q. Or are they, I should say?

7 A. I don't know that they all are,  
8 no. There are -- there are -- I don't think  
9 I have attempted to quantify large in this  
10 sentence.

11 What I'm stating here is not an  
12 issue of large versus small. It's an issue  
13 of the fact that there are toxic effects with  
14 single exposures. And I'm just making the  
15 comment -- this has to do with hazard, right?  
16 It's the idea even a single dose -- or a  
17 single exposure you can get irritant,  
18 inflammatory reactions at the site of  
19 exposure. And that's all I'm trying to say.  
20 That's why I'm citing as reviewed by EPA. I  
21 believe EPA even makes a very similar  
22 statement.

23 Q. Okay. Do you take into  
24 account -- there are some studies for  
25 which -- at least my reading of your report

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1       is that you give them less weight because you  
2       believe that the individuals who conducted  
3       the study had been paid by either a company  
4       or agencies that had some investment in the  
5       outcome of the study; is that correct?

6           A.       Is that my opinion?

7           Q.       Yes.

8           A.       For any particular study,  
9       you'll need to show me what you're pointing  
10      to. I do have opinions about some of the  
11      work by Drs. Huncharek and Muscat, yes. I  
12      think I address that specifically, and that  
13      has -- that's not so much to do with my  
14      weight of the evidence; that has more to do  
15      with transparency and what was being  
16      disseminated to the public and disseminated  
17      to the FDA as far as evaluations.

18                  That's a different issue than  
19      the weight of -- the weight of -- the weight  
20      of the evidence assessment for risk. I think  
21      those were separate.

22           Q.       So then I'll ask you that.

23                  In doing your weight of the  
24      evidence analysis for risk, have you  
25      discounted the weight that you've given to

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1 any particular piece of scientific evidence  
2 based off of potential affiliations of the  
3 authors?

4 A. I certainly did with the CIR  
5 review document. I've already told you that.  
6 And that's because I have evidence that shows  
7 it's not just an affiliation issue, but it's  
8 actually -- it's more -- it's more important  
9 than that.

10 Q. Are there any other examples?

11 A. I think that's the only one  
12 right now as I sit here that I can tell you  
13 that I had identified as carrying little  
14 weight because of an issue of either  
15 authorship or input in the way it was  
16 described.

17 There are certainly studies  
18 within my weight of the evidence evaluation,  
19 some of which were performed by industry. I  
20 certainly look at that issue, but unless I  
21 have -- have a reason to believe that there's  
22 an inherent bias based on something I know,  
23 they go into the weight of the evidence  
24 without making a correction for that.

25 In many cases that I work in

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1 litigation, I will find situations like the  
2 situation here with Huncharek and Muscat  
3 where I have, for example -- I think this  
4 came up in the Risperdal litigation for me.  
5 It's the idea that there was a series of  
6 papers put out by an individual investigator  
7 where documents that I could get access to  
8 show me that indeed their analysis was not  
9 done by them but it was ghostwritten by  
10 somebody else. So that gives me pause,  
11 although I would never have known that unless  
12 I had access to internal documents.

13 So initial weight of the  
14 evidence I did not discount it, but then I  
15 went back and had to reevaluate the role  
16 those studies played in my overall  
17 assessment.

18 Q. Do you take into account in any  
19 way in evaluating the weight of a study if it  
20 is conducted by someone who serves as an  
21 expert on behalf of the plaintiffs in the  
22 active litigation?

23 A. It would be the same -- same  
24 issue. I certainly consider it as part of  
25 what I look at, but just like if they were an

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1 expert for the defense versus an expert for  
2 the plaintiff, you judge that information  
3 based on what you know. And if I don't have  
4 information to discount it, I will not  
5 discount it.

6 But absolutely, I understand.  
7 Just as people we all -- look at some of the  
8 things I've published where I have said my  
9 work was sponsored by the American Chemistry  
10 Council. You know, people -- that's why you  
11 disclose the conflicts. You put it there so  
12 people can weigh it if they want, but it  
13 doesn't mean you discount the work  
14 automatically.

15 And so I think for any paper,  
16 plaintiff, defense, whoever it is that's  
17 writing it, you need to consider it based on  
18 the information you have. And if you believe  
19 that you have information to indicate that  
20 there's some issue with the reliability of  
21 the analysis, then absolutely you consider  
22 that.

23 Q. So, for example, when you rely  
24 on Dr. Longo's characterization of the  
25 constituent components in samples that he has

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1 tested, that he reports are Johnson's baby  
2 powder, did you also consider the work that  
3 was done by experts that have been retained  
4 on behalf of the defendants to characterize  
5 the components of Johnson's baby powder? Do  
6 you give them equal weight?

7 A. So I haven't seen a variety of  
8 the documents that you're talking about,  
9 so -- because I have not worked in the  
10 litigation cases that have involved asbestos  
11 only. So -- which I think is where those  
12 documents are.

13 In the litigation I -- in the  
14 litigation I worked in, I am aware of what  
15 other experts on both sides have said. I  
16 don't believe I've seen an analysis from a  
17 defense expert that is -- that is like  
18 Dr. Longo's, at least in the litigation I've  
19 worked in. Certainly I would consider that  
20 and look at that if it's available, and I  
21 would consider it.

22 I would point out, Dr. Longo's  
23 analysis is not the piece of evidence that  
24 you start with, though. You start with what  
25 I discuss in the published literature first,

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1 because there are published documents out  
2 there in the literature that describe exactly  
3 what Dr. Longo is now describing.

4 Q. What published documents are  
5 those?

6 A. Those are Dr. Blount's reports  
7 in 1991, which is before the litigation came  
8 about, is my understanding.

9 There's also -- there's five or  
10 six. I can tell you the paragraph.

11 Q. For Johnson's baby powder, I  
12 would be interested in that, yes.

13 A. So I -- I'll have to look and  
14 see if it's Johnson's baby powder only, but  
15 certainly there is other evidence on the  
16 issue of asbestos contamination and  
17 specifically in talc.

18 So I -- you want me to find the  
19 paragraph for you?

20 Q. Please. If you think there is  
21 published literature documenting asbestos in  
22 Johnson's baby powder, I would like to see  
23 that.

24 A. So this is my paragraph 32.  
25 And I'd have to pull each of these articles

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1 out because I don't recall what each of them  
2 says. But I'm pointing to Paoletti, Blount,  
3 Mattenkrott, Moon, Gordon, Anderson, Rohl,  
4 Pooley and Rowlands, Blejer and Arlon,  
5 Cralley, Millman.

6 And then I cite -- and then of  
7 course the next piece of evidence is there  
8 are actually documents from J&J and Imerys  
9 that show detection of asbestos or  
10 asbestos-like minerals in talc.

11 Q. As you sit here today, can you  
12 identify which of these published articles  
13 that you list in paragraph 32 relate to  
14 Johnson's baby powder?

15 A. I would have to pull them to  
16 answer that.

17 Q. Okay.

18 A. As I sit here, I'd have to pull  
19 them. But I would refer you -- I know at  
20 least some of them do based on the statement  
21 I've made, but...

22 Q. So you did not make an attempt  
23 in this paper to identify which products were  
24 being analyzed in these specific articles.  
25 It's not indicated on the face of this

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1 paragraph, correct?

2 A. I don't tell you on the face,  
3 but you if read the sentence I said, "When  
4 commercially available, talcum powder  
5 products were analyzed, including powders  
6 sold by Johnson & Johnson. The data has  
7 shown that the powders contained varied  
8 levels" -- and I'm saying "fibers," so it's  
9 just asbestos -- "including fibers that  
10 stated to be asbestos."

11 So to tell you which of those,  
12 I'd have to pull them. And I apologize, I  
13 didn't bring them all with me.

14 Q. Have you been provided --  
15 you're aware that Dr. Blount's paper does not  
16 identify Johnson's baby powder in the face of  
17 the article, correct?

18 A. I believe that's true. You'd  
19 have to go to her deposition, I believe,  
20 where she's given -- where she discusses what  
21 the source of that was, and maybe even a --  
22 there may even be a separate document,  
23 actually, not a deposition, that was -- that  
24 was in the files of Johnson & Johnson that  
25 goes along with that, but I'd have to go

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1 look.

2 Q. Have you reviewed Dr. Blount's  
3 deposition?

4 A. I have reviewed a -- something  
5 by Dr. Blount. Whether it was trial  
6 testimony or deposition, I have seen  
7 something, yes, that she has said regarding  
8 this issue.

9 Q. To the extent that there is  
10 confusion about whether or not a sample  
11 tested by Dr. Blount is in fact Johnson's  
12 baby powder, would you reduce the weight that  
13 you give that particular piece of evidence in  
14 evaluating whether asbestos has been present  
15 in Johnson's baby powder?

16 MS. PARFITT: Objection. Form.

17 MR. MEADOWS: Objection.

18 THE WITNESS: I don't know  
19 reduce the weight because -- because  
20 there's -- there are plenty of  
21 documents here that talk about that.

22 I would consider it --  
23 certainly it would -- it's not so much  
24 weight. It's a different bin. We'll  
25 call it a bin, a different bin of

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1 information. There's information on  
2 talc powders generally, and then  
3 there's some information that's  
4 specific to certain body powders.

5 So certainly -- would I pay  
6 attention if they identified it? Yes.

7 But in the statement I'm making  
8 here, I'm not claiming that every one  
9 of these is relating to just the  
10 powder sold by Johnson & Johnson.

11 This is across the available  
12 information that's public and then  
13 also the information that's available  
14 in the files of Johnson & Johnson.

15 QUESTIONS BY MS. BRANSCOME:

16 Q. What is your definition of  
17 asbestos?

18 A. My definition of asbestos is  
19 exactly what the different documents describe  
20 it typically. It's a fibrous mineral,  
21 typically. It occurs in a variety of  
22 different forms. Most of the times they'll  
23 say "asbestos." Sometimes they'll say  
24 "chrysotile." Sometimes they'll say  
25 "tremolite." Sometimes they'll say

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1 "anthophyllite." Those are the three most  
2 common ones I see. But those are all mineral  
3 forms of asbestos.

4 So just like IARC puts those  
5 all within one bin, I'm putting those all in  
6 one bin because they have a similar toxicity  
7 profile.

8 Q. Is it your view that each of  
9 the different types of asbestos has the same  
10 toxicity profile?

11 A. They all have the same ability  
12 to cause cancer, but they have different  
13 potencies. So they do have -- there will be  
14 some differences in the dose response and the  
15 potency of them, but certainly they've all  
16 been linked as being carcinogens by IARC.

17 And I would agree, when you  
18 look at their data, there is data and  
19 evidence to indicate that.

20 Q. Which type of asbestos is the  
21 most potent?

22 A. For which end point? For lung  
23 cancer? I believe chrysotile is. For other  
24 end points, I'd have to go look. I mean,  
25 chrysotile is the sharp -- is the sharp --

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1 the sharded-type structure.

2 But there's data on fibrous --

3 the fiber -- the fibrous forms of asbestos  
4 rather than the -- or the amphibole forms of  
5 asbestos as opposed to chrysotile, which is  
6 the serpentine form.

7 Q. Do you consider yourself an  
8 expert in asbestos?

9 A. Not in --

10 MS. PARFITT: Objection.

11 THE WITNESS: Not the geology  
12 of asbestos, no.

13 I have expertise in toxicology  
14 as it relates to interpretation of the  
15 data related to asbestos. I have  
16 never give -- given testimony in a  
17 case on asbestos, but it's something  
18 I've studied in the past in my work as  
19 a toxicologist, not as a testifying  
20 expert.

21 QUESTIONS BY MS. BRANSCOME:

22 Q. What role does your analysis of  
23 the possibility that there may be asbestos in  
24 Johnson's talcum powder products play in your  
25 risk assessment in the MDL?

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1                   A.         Has to do with the fact that we  
2 have a complex mixture that has multiple  
3 carcinogenic substances.

4                   And asbestos is important from  
5 the aspect of the way that it has been  
6 assessed even by regulatory bodies, the idea  
7 that even very low levels of fibers pose a  
8 cancer hazard and a cancer risk in  
9 individuals have been shown to be  
10 carcinogenic.

11                  So that's what I'm saying about  
12 potency of asbestos is different than potency  
13 of some other carcinogens that you might look  
14 at. But the importance of it is it's a  
15 complex mixture, talc, body powders, a  
16 complex mixture that includes constituents  
17 that are known human carcinogens as well as  
18 some that are -- been ranked other ways by  
19 regulatory bodies.

20                  Q.         If Johnson's talcum powder  
21 products do not contain asbestos, does that  
22 change your opinion with respect to the risk  
23 they pose with respect to ovarian cancer?

24                  A.         No, and I think that was very  
25 clear if you looked at my first report. So

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1 even -- there's -- I don't think in any of my  
2 reports I've opined that without looking at  
3 the complex mixture that we wouldn't be here.

4 In other words, I have not  
5 opined that if it doesn't have -- if it  
6 doesn't have asbestos, it's not a risk. I  
7 have not opined that, and I don't believe  
8 that, because I think there is independent  
9 risk for the fact that we have a complex  
10 mixture of talc that has been tested and  
11 shown to be carcinogenic.

12 It's my opinion, I told you --  
13 maybe it wasn't you. I may have told this  
14 yesterday, I'm sorry, to Mr. Smith that I  
15 believe that there is evidence to show that  
16 there is a significant exposure to asbestos  
17 based on the data that's been collected.

18 But certainly, you know, in  
19 some -- the data has shown that in the assays  
20 that have been done or the analyses that have  
21 been done that you can't say that talc is  
22 asbestos-free.

23 Q. Well, so --

24 A. So --

25 Q. -- the question I have

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1 specifically relates to ovarian cancer.

2 Is it your view that through an  
3 exposure route that is relevant for ovarian  
4 cancer, that the use of Johnson's talcum  
5 products involve a substantial exposure to  
6 asbestos?

7 A. I believe based on the use of  
8 the products that -- where the data has been  
9 collected that there would be a substantial  
10 exposure to asbestos, regardless of how  
11 you're exposed, perineal -- perineally or by  
12 inhalation.

13 Q. What is your basis for reaching  
14 that conclusion?

15 A. It's looking at the number of  
16 fibers that have been detected in the  
17 products, in looking at the -- the widespread  
18 nature of the presence of asbestos fiber --  
19 asbestos in the talcum powder products and  
20 the fact that even though it's at a very low  
21 level by their -- their level of detection,  
22 again, can't be said to be asbestos-free.

23 So regardless of whether it's  
24 talc that's being applied perineally or a  
25 talc that you're inhaling while you're

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1 applying it perineally, the fibers are still  
2 going to be present within that talc.

3 Q. Have you or anyone done an  
4 analysis of the dose of asbestos to which  
5 someone might be exposed perineally?

6 A. I haven't done a specific  
7 calculation, no.

8 Q. Has anyone done that  
9 calculation?

10 MS. PARFITT: Objection. Form.

11 QUESTIONS BY MS. BRANSCOME:

12 Q. That you have seen?

13 MS. PARFITT: Objection.

14 THE WITNESS: I'm trying to  
15 remember whether I saw that done in  
16 any of the documents related to  
17 Dr. Longo.

18 I don't know. I'd have to go  
19 look.

20 QUESTIONS BY MS. BRANSCOME:

21 Q. Okay. So as you sit here  
22 today, can you give an opinion to a  
23 scientific degree of certainty, reasonable  
24 degree of scientific certainty, that an  
25 individual would be exposed to a dose of

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1 asbestos above background through the  
2 perineal use of Johnson's talcum powder  
3 products?

4 MR. MEADOWS: Objection.

5 MS. PARFITT: Objection.

24 QUESTIONS BY MS. BRANSCOME:

25 O. Okay.

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1           A.       So that's -- so that's a  
2 different question I have not answered.

3           Q.       And in reaching your opinion  
4 that there is no evidence that asbestos-free  
5 talc exists, you have not been provided with  
6 the reports by the defense experts, including  
7 Dr. Matthew Sanchez, analyzing Johnson's  
8 talcum powder products for the presence or  
9 absence of asbestos, correct?

10           MS. PARFITT: Objection. Form.

11           I think you're aware that the  
12 MDL expert reports have not yet been  
13 provided to us.

14           MS. BRANSCOME: Yeah.

15           MS. PARFITT: I'm just making a  
16 point.

17           THE WITNESS: I have not seen a  
18 report by Dr. Sanchez. I assume I  
19 will, because typically after -- later  
20 in the litigation, once all experts  
21 have been deposed or revealed, I'm  
22 usually given defense expert reports  
23 and their deposition testimony. So I  
24 expect to see that; I just haven't  
25 seen it yet.

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1       QUESTIONS BY MS. BRANSCOME:

2           Q.       And you haven't seen it in any  
3       of the cases in which you've rendered an  
4       opinion, correct, not just the MDL?

5           A.       Well, none of the cases that I  
6       have worked in have involved the issue of  
7       looking for asbestos exposure.

8                   The cases I have worked on have  
9       been talking about talc exposure that may  
10      include asbestos as a constituent, but it  
11      wasn't focused on asbestos exposure.

12                  So, no, none of the cases I  
13       worked on have provided testimony in that  
14       area.

15                  You understand what I'm saying?

16           Q.       Let me just make it clear. You  
17       have not, in any of the cases in which you  
18       have offered opinions with respect to the  
19       contents of talc, been provided with an  
20       expert report or testimony by Dr. Sanchez  
21       about what he did or did not find in  
22       Johnson's talcum powder products with respect  
23       to asbestos?

24                  MS. PARFITT: Objection. Form.

25                  THE WITNESS: So I can't tell

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1           you that I have not. I don't recall  
2           it. That's all I can say. I don't  
3           recall that name.

4       QUESTIONS BY MS. BRANSCOME:

5           Q.     It's certainly not something  
6       you discuss in your report, correct?

7           A.     No, I do not. And I don't know  
8       that it's in my reliance materials. That's  
9       why I'd ask you to look there, because if  
10      it's in my reliance materials, then I've seen  
11      it.

12          Q.     Okay.

13          A.     And I mean big reliance  
14       material list, not my reference list.

15          Q.     All right. With respect to the  
16       other potential constituents of talc, have  
17       you done any analysis to provide an answer as  
18       to how much -- what dose of chromium, for  
19       example, an individual might be exposed to  
20       through the perineal use of Johnson's talcum  
21       powder products over a lifetime?

22          A.     No, and I have -- well, I know  
23       it's a separate deposition. We discussed  
24       this yesterday. No, I have not done a -- a  
25       calculation of a potential dose with perineal

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1 application for any of the heavy metals. So  
2 the three that I've mentioned, no, I have not  
3 done that calculation.

4 Q. You would agree, based on your  
5 training and experience as a toxicologist,  
6 that in order for an agent -- and we can talk  
7 specifically about a metal -- to present a  
8 risk of cancer it needs to be bioaccessible,  
9 correct?

10 A. If by bioaccessible you are not  
11 limiting that definition to solubilized into  
12 the blood and carried systematically, yes, I  
13 would agree with that. Bioaccessible meaning  
14 it has to be in a form that can somehow  
15 interact with the tissue, yes, I agree with  
16 that. But it could be as simple as tissue  
17 contact versus needing to be solubilized.

18 Q. Okay. Is silica bioaccessible?

19 A. It depends on the form of the  
20 silica. So silica particles can be  
21 bioaccessible if inhaled and found on the  
22 surface of the lung. That can cause injury  
23 at the site of the lung. So that's an  
24 accessibility to that particular tissue that  
25 it contacts.

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1 Q. We talked earlier -- it's  
2 somewhat related to bioaccessibility, but we  
3 talked about the way in which different  
4 particles might move specifically through the  
5 genital tract in women.

6 Do you recall that?

7 A. Yes. A general discussion.

8 Q. Yes.

9 And when you testified that  
10 starch and talc might not move at the same  
11 rate, do you have an opinion as to which  
12 might move more quickly through the tract?

13 A. I haven't formed that opinion,  
14 no.

15 Q. Okay. And do both talc and  
16 starch particles remain in the body for the  
17 same length of time?

18 A. I haven't done an analysis to  
19 see if the data tells us what the -- what the  
20 differences might be. I would expect there  
21 to be differences, which is what I told you  
22 earlier, because I would expect the starch to  
23 be able to be solubilized, where I would not  
24 necessarily expect the talc to act in that  
25 same manner.

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1           Q.       Is cornstarch capable of  
2       causing an inflammatory process?

3           A.       It can. It is -- but it is --  
4       it's a different level of risk for  
5       inflammatory responses than is talc, just by  
6       its chemical nature.

7           Q.       Have you done an analysis in  
8       your report that examines the differences  
9       between the inflammatory response that can be  
10      triggered by talc as opposed to cornstarch?

11          A.       I haven't analyzed inflammatory  
12       response. Instead, what I've done is done a  
13       comparison of what the toxicity -- the  
14       differences in the toxicity potential have  
15       been described in medical literature, and I  
16       cite -- I have a paragraph where I cite to  
17       some sources that talk about the differences  
18       in the toxicity potential or biocompatibility  
19       of starch versus talc.

20          Q.       Now, I had a question about  
21       your supplemental report that was marked as  
22       Exhibit 3 to the deposition.

23                   At paragraph 67...

24          A.       Okay.

25          Q.       You identify here six heavy

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1 metals - arsenic, chromium, lead, cobalt,  
2 cadmium and nickel - that in your  
3 supplemental report dated August 29, 2018,  
4 you say have been reported across lots of  
5 talc powders.

6 Do you see that?

7 A. Are you in -- now you're in my  
8 MDL report or here?

9 Q. No.

10 A. Oh, so where are you? I'm  
11 sorry.

12 Q. Same report. It's the sentence  
13 that begins at the bottom of page 6.

14 A. Okay. Hold on.

15 About that they have varied at  
16 the levels --

17 Q. Yes. So you identify six  
18 different types of heavy metals.

19 Do you see that there?

20 A. Yes, I do.

21 Q. Okay. And the question I had  
22 for you was that in your report in the MDL,  
23 if you look at paragraph 36 --

24 A. Yes.

25 Q. -- you identify -- you identify

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1 only three heavy metals: chromium, cobalt  
2 and nickel.

3 Do you see that?

4 A. Yes.

5 Q. Why did you remove three of the  
6 heavy metals?

7 A. It's not so much removing.

8 Those three heavy metals that I focused on in  
9 my MDL report are ones that have been talked  
10 about with a similar mechanism of action as  
11 far as irritation and biologic -- biologic  
12 plausibility mechanism being irritation and  
13 inflammation.

14 So that's why I focus on those  
15 three, which may not -- which is not  
16 necessarily the case for some of the others,  
17 even though they're also -- have a  
18 carcinogenic hazard, pose a risk.

19 Q. So in your -- as part of your  
20 risk assessment that you performed in the  
21 MDL, are you offering the opinion that to the  
22 extent they exist in any of the Johnson  
23 talcum powder products, that arsenic, lead --

24 A. Cadmium.

25 Q. -- and cadmium play any role in

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1 the risk of developing ovarian cancer?

2 A. That is not an opinion that I  
3 would be offering in the MDL.

4 Q. Okay. Now, you talk about  
5 these heavy metals having been classified by  
6 different agencies as either known probable  
7 or possible human carcinogens, correct?

8 A. You're in my MDL report again?

9 Q. Oh, yes.

10 A. Okay. I'm sorry. Okay. Let  
11 me get there.

12 Yeah, I do have that  
13 discussion. I'm just trying to find it.

14 Q. Sure.

15 A. Okay. Yes, I'm there.

16 Q. Is it your view, based on your  
17 expertise, that because a compound can cause  
18 one type of cancer, it can cause all types of  
19 cancer?

20 A. No, not necessarily. It  
21 depends on the -- well, it depends on a  
22 couple of things. It depends on what's been  
23 studied. Have all types of cancer even been  
24 studied. And then it also -- it also depends  
25 upon, I believe, the route of exposure as

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1 well. So can it get to where it could cause  
2 that, could it distribute there. And then in  
3 addition to that, what data has been  
4 collected. Is there enough data, for  
5 example, to show that there's extrapolation  
6 from animals to humans in the types of tumors  
7 or is it -- or if we have good human data,  
8 then we would focus on the types of cancers  
9 that you're seeing in humans, for example.

10 Q. Okay. But you recognize even  
11 where there is complete data some compounds  
12 can cause one type of cancer and they are  
13 incapable of causing another type, correct?

14 MS. PARFITT: Objection. Form.

15 THE WITNESS: I don't know  
16 about incapable, but I would agree  
17 that you certainly would see -- you  
18 could potentially see different  
19 observations.

20 If you're talking about animals  
21 versus humans, or are you talking  
22 about --

23 QUESTIONS BY MS. BRANSCOME:

24 Q. If humans.

25 A. Based on what you had seen in

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1 the animals; is that what you're asking me?

2 Q. Yes.

3 A. Yes. So, yes, there is not  
4 always a one-to-one concordance. So that's  
5 why -- that's why I made the comment that  
6 it's important to have some human data or  
7 experience, so that you can put in context  
8 the data you collected in animals.

9 I would say to you there are  
10 certain kinds of tumors in animals, for  
11 example, that are shown to be not relevant at  
12 all to human risk assessment. Like four  
13 stomach tumors in rats is an example. I've  
14 dealt with that one a lot.

15 Q. What types of cancer -- type or  
16 types of cancer are the basis for the  
17 classification of chromium as a known human  
18 carcinogen by IARC?

19 A. So I have to pull it out, but I  
20 believe that there may be some GI cancers and  
21 maybe some skin cancers, but I'm not sure.  
22 I've got it pull it out. It's been a while  
23 since I've looked at it.

24 Q. Okay. Have you done an  
25 analysis to evaluate whether or not the types

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1 you can extrapolate with scientific basis  
2 from one type of cancer cause to ovarian  
3 cancer with respect to the heavy metals  
4 specifically?

5 A. Well, I haven't attempted to  
6 that, because I haven't attempted to define a  
7 independent risk for each of those metals  
8 individually.

9 The issue -- the issue I have  
10 with those metals is -- there's a paragraph  
11 here where I talk about pathogenesis of  
12 carcinogenesis, where I talk about different  
13 stages of cancer development and the fact  
14 that inflammatory responses may be operating  
15 at all those different stages.

16 So the issue is you have  
17 potential -- you have compounds that are  
18 known to produce cancer or have been shown to  
19 have a potential risk of cancer. They share  
20 a similar mechanism to talc, so as a result  
21 of that, they factor into your risk  
22 assessment as far as there being an exposure  
23 to a mixture.

24 But on the issue of ovarian  
25 cancer, I'm looking at the data that's been

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1       collected on talc itself, which would be talc  
2       with the constituents that could include the  
3       metals. But certainly I'm not saying that it  
4       is -- without the presence of one or the  
5       other of these there would be no risk of  
6       ovarian cancer. I'm not saying that either.

7           Q.       So my question is, though, can  
8       you point me either to scientific literature  
9       directly documenting that these heavy metals  
10      can cause ovarian cancer or to scientific  
11      literature that enables you to extrapolate  
12      from the types of cancer that they are known  
13      or believed to cause to ovarian cancer?

14          A.        So I -- on the issue of can I  
15       point you to the data on ovarian cancer, I'd  
16       have to go back. I can't answer that without  
17       looking at the assessments.

18               But on the other -- second  
19       question you asked me, that's the question I  
20       was just trying to answer before. It's the  
21       idea that regardless of where the cancer is  
22       developing, the fact that these compounds  
23       have the ability to stimulate similar toxic  
24       responses in tissues could lead to a --  
25       setting up a situation where the -- where the

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1 tissue is primed for cancer development.

2 Q. And do you have --

3 A. And so that --

4 Q. Sorry.

5 A. And that has to do with the  
6 basic science of carcinogenesis when you look  
7 at underlying mechanisms, especially with  
8 tissue contact, direct tissue contact, with  
9 irritants or inflammatory processes.

10 But I would -- I am not -- I  
11 have not formed the opinion, again, that with  
12 or without either one of these that I would  
13 expect ovarian cancer to be the target. I'm  
14 saying that ovarian cancer risk is increased  
15 based on exposure to talc, which includes a  
16 variety of constituents.

17 Q. Okay. And do you cite anywhere  
18 in your report to studies documenting -- I  
19 know you said you'd need to go look at them,  
20 but I'm asking if it's in your report  
21 anywhere a discussion of any studies showing  
22 that the particular heavy metals that you  
23 cite as potential constituents of Johnson &  
24 Johnson's products have been demonstrated to  
25 increase a risk for ovarian cancer on their

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1 own?

2 A. So, no, I haven't addressed  
3 that in my report. And again, I think that's  
4 inconsistent with the way I'm using these  
5 data. But that's fine. I mean, no, I  
6 haven't done a specific assessment of ovarian  
7 cancer risk with each of those metals  
8 individually.

9 Q. I would ask the same questions  
10 for the different fragrance constituents that  
11 you allege in your report are potential  
12 carcinogens.

13 Have you done any analysis, and  
14 can you point me to any scientific studies  
15 that establish that those particular  
16 compounds are capable of causing ovarian  
17 cancer?

18 A. No, I haven't done that  
19 analysis, but, again, general principles of  
20 toxicology and cancer risk assessment, when  
21 you look at the presence of multiple --  
22 excuse me, multiple carcinogens with similar  
23 mechanisms of action, you would assume in  
24 your risk assessment that those risks could  
25 be additive.

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1 So, again, that's what I'm  
2 pointing to and why I have cited the data.

3 Q. Now, you talked about -- when  
4 we were discussing mechanism, you said that  
5 inflammation alone is not necessarily  
6 sufficient to cause cancer, correct?

7 A. Yes, I did.

8 Q. All right. Do you have  
9 scientific studies that show that any of the  
10 heavy metals or the fragrance constituents  
11 that you identify as potential carcinogens  
12 create -- generate phenotypic changes like  
13 you discussed were next for the formation of  
14 cancer?

15           A.       I believe that data is  
16   available on nickel. I need to go back and  
17   look at chromium and cobalt, but I do believe  
18   with nickel you'll find similar data on  
19   tissue irritation and inflammatory processes.

Nickel is also a sensitizer, so  
it has interaction with the immune system, so  
I do believe that for nickel you can find  
some of that data.

Q. Okay. But as you sit here today, can you point me into any of that

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1       that's discussed in your report?

2           A.       No specific discussion other  
3       than, again, all -- the IARC -- I'm citing to  
4       the IARC assessments, and the IARC  
5       assessments for each of those discuss  
6       carcinogenesis and a biologically plausible  
7       mechanism being linked to the ability of  
8       these compounds to induce oxidative stress  
9       and/or inflammatory processes.

10          Q.       Okay. In your opinion, you  
11       talk about the mixture of constituents that  
12       are involved in talc.

13               Have you done any analysis to  
14       look at how the different constituents  
15       interact with each other?

16          A.       Well, yes, that's my issue at  
17       looking at underlying mechanism.

18               But are you asking me -- I  
19       certainly don't have a -- the only studies  
20       that I have to rely upon on the interaction  
21       of the mixture is the actual studies on the  
22       powders themselves, where we know that the  
23       powders contain constituents other than just  
24       platy talc.

25          Q.       Okay. And do the constituents

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1 need to have the same underlying potential  
2 carcinogenic mechanism for them to have an  
3 additive effect?

4           A.       By general principles of  
5 toxicology, yes, you look at mode -- mode of  
6 action or mechanism of action before you  
7 apply that additivity principle to the cancer  
8 risk assessment.

9           Q.       And so as you sit here, you  
10 believe there have been scientific  
11 documentation that nickel might operate  
12 through the same biological mechanism as you  
13 purport talc to operate, but you're not sure  
14 about the other heavy metals or the fragrance  
15 constituents; is that correct?

16           MS. PARFITT: Objection.

17           THE WITNESS: For the fragrance  
18 constituents, I'd definitely have to  
19 pull because I haven't looked at that  
20 individual assessment in a while.

21           For these three, what I do know  
22 is that they do share the ability to  
23 at least induce oxidative stress.

24           What I can't recall for  
25 chromium and for cobalt is whether

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1           they're taking it the next step from  
2           oxidative stress to inflammatory  
3           process. I believe that they do, but  
4           I'd have to check, whereas I know  
5           nickel has been shown to lead to an  
6           inflammatory process after oxidative  
7           stress has been induced.

8        QUESTIONS BY MS. BRANSCOME:

9           Q.       And you would agree, even more  
10          than requiring an inflammatory process, you  
11          would actually have to see that these  
12          compounds can generate phenotypic changes,  
13          correct?

14           MS. PARFITT: Objection.

15           THE WITNESS: Well, we know  
16          they do because they've been shown to  
17          be carcinogenic. If you've been shown  
18          to be carcinogenic, you've done a  
19          phenotypic change in the cell from a  
20          normal cell to a cancer cell.

21           So we know they have the  
22          capability to induce tumors, or  
23          cancer, all three of those, at least  
24          in animals if not in humans as well,  
25          because two of them are known human.

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1           So those two -- we'd have human data  
2           to show that.

3                 But on the issue of cobalt, it  
4                 may only be -- I need to go back and  
5                 look, but it may indeed just be animal  
6                 data.

7     QUESTIONS BY MS. BRANSCOME:

8           Q.         And so your basis for that  
9                 would be the IARC classification?

10                 Is that where I would go to  
11                 look if I wanted to look at it after this  
12                 deposition?

13           A.         I'd go to the IARC reviews.  
14                 I'd go to those three which I believe I have  
15                 cited down here for you and given you where  
16                 to go to find them.

17           Q.         Okay. You discuss in your  
18                 report -- and if you'd like to reference it,  
19                 it's paragraph 69 on page 47 -- the concept  
20                 of genotoxic and nongenotoxic carcinogens.

21                 Do you recall that?

22           A.         Yes.

23           Q.         And as you sit here today, is  
24                 it your opinion that talc is more likely a  
25                 nongenotoxic carcinogen?

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1                   A.         As the direct insult, yes. And  
2 I would like to -- I would like to point out  
3 that in the literature -- the reason I have  
4 this paragraph here is because in the  
5 literature in the past, in the area of  
6 chemicals, it's been -- toxicologists have  
7 attempted to put two bins, direct genotoxic  
8 insult versus nondirect genotoxic. It  
9 doesn't mean you can't get a genotoxic event  
10 after the initiation.

11                   So I want to make sure you  
12 understand that. I'm not saying that there  
13 is no possibility of this chemical in its --  
14 in its process of inducing cancer leading to  
15 indirect genotoxicity, but I'm talking about  
16 the direct mechanism at the site of the cell.

17                   So talc, for example, has been  
18 shown to not be genotoxic in cells. And so  
19 that's why I believe, then, when I look at  
20 the rest of the data that fits, that it fits  
21 the definition of a nongenotoxic carcinogen  
22 by its initial mechanisms to induce cancer.

23                   Q.         Okay. And if talc is, in fact,  
24 a nongenotoxic carcinogen, it would suggest  
25 that there is likely a threshold dose below

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1 which it does not have a carcinogenic effect,  
2 correct?

3 MS. PARFITT: Objection.

4 THE WITNESS: It is possible,  
5 and that's the problem. In order to  
6 fully assess that, you would have to  
7 have the data to prove it.

8 But that's the assumption. You  
9 assume with nongenotoxic carcinogens  
10 that you could identify a level where  
11 you wouldn't turn on that indirect  
12 mechanism. So that -- yes, that is  
13 true.

14 QUESTIONS BY MS. BRANSCOME:

15 Q. And you have not been able to  
16 identify, nor can you point to, scientific  
17 literature that identifies a threshold -- a  
18 threshold dose for talc with respect to its  
19 carcinogenic potential for ovarian cancer,  
20 correct?

21 A. Not a specific dose, but I  
22 think that's why I mentioned to you -- and  
23 I -- I think that's why Canada, when you look  
24 at their document, they talk about  
25 discouraging routine use generally. So it's

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1 the issue of what -- single use of a body  
2 powder or an occasional use is a different  
3 risk assessment than routine use.

4 So if you want to talk about  
5 thresholds that way, that's very imprecise,  
6 but you could do that. You can talk about  
7 whether or not there -- I do believe there's  
8 a different risk profile for one or two uses  
9 of talc body powder versus a risk profile of  
10 somebody who uses it routinely, because I  
11 think that fits that threshold definition.  
12 It's the idea that you have limited  
13 availability for enough particles to migrate  
14 to lead to the tissue toxicity that it cannot  
15 be recovered from or repair.

16 Q. You're familiar with the  
17 concept of the precautionary principle,  
18 correct?

19 A. Yes.

20 Q. All right. And you understand  
21 that Health Canada may have made  
22 recommendations with respect to product usage  
23 that are purely precautionary, correct?

24 MS. PARFITT: Objection. Form.

25 THE WITNESS: I disagree that's

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1           what they've done, but is it possible  
2           that they would do it? Any regulatory  
3           agency, it's possible they could do  
4           it, yes.

5        QUESTIONS BY MS. BRANSCOME:

6           Q.       Do you have any information  
7        with respect to Health Canada's  
8        decision-making, other than what you have  
9        read on the face of the documents?

10          A.       That is all I have to look at  
11        is what is provided on the website.

12          Q.       Okay. And so the statement  
13        that you think Health Canada was suggesting a  
14        dose threshold by their statement of  
15        discouraging routine use, you're basing that  
16        entirely on what you read on the piece of  
17        paper, correct?

18                   MS. PARFITT: Objection. Form.

19                   THE WITNESS: Well, that's what  
20        they state. So, yes, I'm -- I am  
21        telling you what I see on their  
22        website. If that's what you're asking  
23        me, yes, that is true.

24        QUESTIONS BY MS. BRANSCOME:

25          Q.       Okay. Can you point me --

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1 well, do you discuss -- have you looked at,  
2 as part of your opinion specifically in the  
3 MDL, the studies exploring a potential link  
4 between asbestos and ovarian cancer? Just  
5 asbestos.

6 A. Some of the studies, yes, but I  
7 have not -- I have not done a separate risk  
8 assessment just for asbestos by itself,  
9 because I have not assumed that there is  
10 asbestos-only exposure.

11 Does that make sense?

12 But I do cite -- for example, I  
13 cite to some of the early literature on -- so  
14 this -- I guess where this opinion comes in  
15 is on hazard and warning. So in the warnings  
16 I talk about when it was known that asbestos  
17 was linked with cancer, because the warning  
18 standard is not causation proven but the  
19 identification of the potential. And so that  
20 is in my report on warnings, but that is not  
21 within my discussion of the weight of the  
22 evidence for risk assessment of the talc  
23 product.

24 Q. Okay.

25 A. Does that make sense?

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1 Q. Uh-huh.

2 For example, have you rendered  
3 an opinion about what dose of asbestos  
4 exposure would be necessary to cause ovarian  
5 cancer in an individual?

6 A. No, I have not formed that  
7 opinion at this time.

8 Q. Okay. Do you have an opinion  
9 about the background level of asbestos to  
10 which individuals are exposed with no  
11 increased risk of any type of cancer?

12 A. No, I do not have an opinion.  
13 I do believe others do, but I do not.

14 Q. Okay. You may have been asked  
15 some of these questions before, but I will  
16 keep them brief.

17 Have you ever published any  
18 articles that state that talc causes ovarian  
19 cancer?

20 A. No, I have not.

21 Q. Have you ever publicly  
22 expressed the opinion that talc increases the  
23 risk of ovarian cancer outside of literature?

24 A. No. My work has been in the --  
25 in the courtroom.

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1 MS. BRANSCOME: I think we can  
2 take a break.

3 VIDEOGRAPHER: We are going off  
4 the record at 2:57 p.m.

5 (Off the record at 2:57 p.m.)

6 VIDEOGRAPHER: We are back on  
7 the record at 3:13 p.m.

8 MS. BRANSCOME: Dr. Plunkett, I  
9 have no more questions for you on  
10 behalf of Johnson & Johnson, subject  
11 to your counsel doing a direct of any  
12 kind.

13 THE WITNESS: Sure. Thank you.

14 EXAMINATION

15 QUESTIONS BY MS. BOCKUS:

16 Q. Good afternoon, Dr. Plunkett.  
17 You and I have met before. My name is Jane  
18 Bockus, and as you know, I represent Imerys  
19 in this case.

20 A. Yes.

21 Q. Correct?

22 I want to go back to just touch  
23 briefly on a couple of issues that have  
24 already been addressed.

25 Would you agree that IARC has

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1 not classified any of the heavy metals that  
2 you've identified in your MDL report as  
3 carcinogenic to the ovary?

4 A. So the answer is I'd have to  
5 look. I don't recall that, but I'd have to  
6 look to confirm.

7 Q. Okay.

8 A. That's the answer I believe I  
9 gave a few minutes ago, yes.

10 Q. So if I look at the IARC  
11 website, then I can confirm whether or not  
12 they have identified any of those as  
13 carcinogenic to the ovary?

14 A. Not so much the web -- well,  
15 the website or the actual documents. I think  
16 I would actually point you to the actual  
17 monograph --

18 Q. To the monograph.

19 A. -- because there may be  
20 evidence in there of ovarian cancer as being  
21 seen in studies. And I'd have to go look.

22 Q. Okay. That was not part of  
23 your consideration here, correct?

24 A. So ovarian cancer is part of my  
25 consideration, but I didn't -- in this part

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1 of my evaluation I'm trying to -- trying to  
2 describe these metals. And this is really  
3 about mechanism of biologic plausibility and  
4 the fact that these two things can go  
5 together, and then the concept of additivity  
6 is they're on hazard. The idea if you have a  
7 cancer hazard generally and you have similar  
8 mode of action, regardless of the tissue, you  
9 would be expected to have a potential  
10 additive effect when you do a risk  
11 assessment.

12 So that's my use of that data,  
13 which is why I didn't do a separate ovarian  
14 cancer assessment for each of the each  
15 constituents but just on powder.

16 Q. And you discuss that topic on  
17 page 47, paragraph 68, of your report,  
18 correct, the -- whether there's an additive  
19 effect?

20 And you cite to Casarett and  
21 Doull. I don't know if I'm pronouncing those  
22 names correctly.

23 A. I'm sorry, on what page?

24 Q. I'm on page 47, paragraph 68.

25 A. Okay. Sorry. I should know

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1 where it is, but...

2 Okay. I'm there, yes. Okay.

3 Yes, I do cite to a chapter in  
4 Casarett and Doull, yes.

5 Q. Okay. And Casarett and Doull  
6 is a resource that you cite to for a couple  
7 of different toxicological principles that  
8 you discuss in your -- in your report,  
9 correct?

10 A. Yes, because it's one of the  
11 most well-recognized textbooks that is used  
12 across different either universities or  
13 schools or even in regulatory agencies.

14 I would also say I cite EPA  
15 2000 there. I'm not citing just Casarett,  
16 but I am citing Casarett as well as an EPA  
17 guidance document.

18 Q. In Casarett and Doull, do they  
19 actually discuss talcum powder in Chapter 2,  
20 or is it more just the concept of the  
21 potential of the effects when you have two  
22 different chemicals that you're exposed to at  
23 once or three or four?

24 A. It's the latter. It's the --  
25 because you'll notice the title is

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1 "Principles of Toxicology," so it's the  
2 general chapter teaching principles for risk  
3 assessment and toxicology as used in risk  
4 assessment.

5 Q. And whether there is an  
6 additive effect of, say, talc and nickel,  
7 that's something that an experiment could be  
8 designed to study, correct?

9 MS. PARFITT: Objection.

10 THE WITNESS: If you're talking  
11 generally for cancer and not worried  
12 about the issue of ovarian cancer, if  
13 you're talking about cancer, like  
14 doing an inhalation experiment to look  
15 what happens to the lung, that you  
16 could do.

17 The problem with the animal  
18 studies and ovarian cancer due to  
19 perineal exposure is it's very  
20 difficult to understand how you design  
21 a study to expose the animals that way  
22 reliably in the way that humans are  
23 exposed.

24 But generally you could  
25 study -- you might even be able to do

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1           a genetically susceptible mouse study  
2           to hurry the process along to look at,  
3           but you might not be able to do it  
4           through perineal exposure. You might  
5           have to do it through another route  
6           such as either inhalation or maybe  
7           even you could -- you could look at it  
8           through intraperitoneal injections,  
9           for example.

10          QUESTIONS BY MS. BOCKUS:

11           Q.       Well, and what the textbook  
12          talks about is the fact that you need to  
13          study it to find out whether the effects are  
14          additive, whether the effects are something  
15          that multiply the risk, you know, so that the  
16          two together are greater than either one  
17          alone, or do the effects offset each other  
18          and reduce the risk, correct?

19           A.       That is discussed there --

20                   MS. PARFITT: Objection.

21                   THE WITNESS: -- which is why  
22          I've cited the EPA document. Because  
23          the EPA document addresses the issue  
24          of mixtures, and this is the issue of  
25          mode of action. If you have chemicals

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1           that you're looking at on the issue of  
2           additivity or no effect, you will --  
3           you look at that issue of how they're  
4           affecting the tissue and underlying  
5           mechanism.

6           But the only way to look at the  
7           magnitude absolutely of how the risk  
8           would change is by doing an  
9           experiment. That is true.

10          QUESTIONS BY MS. BOCKUS:

11          Q.       And to your knowledge, that  
12         experiment has never been done; is that  
13         correct?

14          A.       I can't guarantee that it's  
15         only been done for nickel and talc alone, but  
16         I would -- I would state that based on --  
17         there are studies out there that have been  
18         done where they've used the body powder that  
19         we know have metals -- a variety of things  
20         within it that are not just platy talc, but  
21         those experiments are that kind of data.

22           But as far as gathering  
23         dose-response information or teasing out  
24         individual components, that is not available.

25          Q.       Do you agree that dose response

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1     is the fundamental principle of toxicology  
2     that underpins the effects that chemicals can  
3     have on living organisms?

4                 A.     When you're talking general  
5     toxicology, yes, I think it's talked about in  
6     the textbook.

7                 Q.     And you agree that it is the  
8     dose of the chemical and the pattern of  
9     exposure that determines whether a chemical  
10    produces an adverse effect on an organism,  
11    not simply the presence of the chemical?

12                A.     For a typical dose-response  
13    relationship for non -- for nongenotoxic  
14    events, absolutely, I would agree that is  
15    probably true. And I don't mean nongeno --  
16    noncancer events.

17                In the issue of cancer biology,  
18    some of those issues don't hold all the time.  
19    In other words, there are certain chemicals  
20    and certain ways of looking at cancer risk  
21    assessment where you can't assume where the  
22    threshold is or identify what a safe dose  
23    would be. But certainly I agree on the issue  
24    of noncancer risk assessment generally, or  
25    general end points of toxicity, that is true.

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1           Q.       And again, do you agree that in  
2 general toxicology the effects that might be  
3 reported at high doses will not occur at  
4 lower doses if the concentration at the site  
5 of action falls below the threshold for  
6 toxicity?

7           A.       Yes, that could -- that could  
8 be possible, yes.

9           Q.       And do you agree that  
10 evidence-based toxicology and epidemiology  
11 dictates that the dose of the chemical is the  
12 critical factor when examining the risk posed  
13 by a chemical, not just its presence even in  
14 the human body?

15          A.       I would say that's generally  
16 true, yes, which is why I have attempted to  
17 look at the dose-response relationship as  
18 well as the prevalence of the contact.

19          Q.       And with regard to the human  
20 studies that you cite, would you agree that  
21 none of the studies that you cite in your  
22 report that have to do with migration of  
23 particles within the genital tract of the  
24 female involve applications to the perineum  
25 or outside of the genital tract?

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1           A.       That is true with the exception  
2       of Parmley and Woodruff, which addresses this  
3       issue of --

4                   MS. PARFITT: Objection.

5                   THE WITNESS: Talks about the  
6       issue of exposure from the outside to  
7       the inside.

8                   But the data that is collected  
9       with the different studies they have  
10      deposited at some point -- at some  
11      position within the vagina, that is  
12      true.

13     QUESTIONS BY MS. BOCKUS:

14     Q.       And that is not how talc is  
15      deposited in women who use it regularly in  
16      their daily routine, correct?

17                   MS. PARFITT: Objection.

18                   Misstates the evidence.

19                   THE WITNESS: So I would say  
20      that depends on what women are doing.  
21      Perineal application, for example,  
22      application on the underwear, can lead  
23      to contact of the vaginal opening  
24      depending on the woman.

25                   For example, a woman who has

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1           a -- had many children has a tract  
2           that is stretched. There, indeed, you  
3           can have more direct contact than you  
4           can with a very tight -- so I would  
5           say it depends on the woman and it  
6           depends on the situation.

7                 But I do think it's generally  
8           accepted, based on my review of the  
9           literature, that there is the  
10          opportunity for exposure internally  
11          from perineal application.

12 QUESTIONS BY MS. BOCKUS:

13           Q.       And if I understand what you  
14          testified to earlier today and yesterday, you  
15          don't have any data that would advise on --  
16          out of the talc that is deposited in the  
17          underwear, what percentage of it makes it  
18          into the reproductive tract?

19           A.       That's the data that's missing,  
20          that is true. And unfortunately, no one has  
21          done a study. It would be -- if there was a  
22          way to do that, it would be interesting to do  
23          that. I just don't see how you design that  
24          study, especially knowing the hazard of talc  
25          at this point. I think that would be a

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1 difficult study to get approval for.

2 Q. And do you have an opinion as  
3 to whether it is even correct that each day  
4 that a woman uses talc in her underwear, that  
5 some of the talc makes its way to the ovary?

6 MS. PARFITT: Objection. Form.

7 THE WITNESS: Have I -- can I  
8 quantify that?

9 No, I haven't quantified it. I  
10 think I got asked that earlier. I  
11 can't quantify the amount that gets  
12 there. Or, I'm sorry, I may have  
13 misheard the start of your question.

14 I apologize.

15 QUESTIONS BY MS. BOCKUS:

16 Q. Yeah, I'm really asking: Do  
17 you have an opinion as to whether it happens  
18 every single time a woman applies talc to her  
19 perineal area? Does some of that talc make  
20 it to her ovary?

21 MR. MEADOWS: Objection.

22 MS. PARFITT: Objection.

23 THE WITNESS: I don't think I  
24 stated it quite that way, but  
25 certainly I think the opportunity is

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1           there with every application. And of  
2           course it would depend upon the amount  
3           of time that the contact may be in  
4           place. But the opportunity is there.

5           So, for example, if you applied  
6           it to your underwear and 30 minutes  
7           later you go to the bathroom, it's  
8           very possible that you will have wiped  
9           away, and so that that application may  
10          have taken an opportunity away. But I  
11          do believe that the opportunity is  
12          there based on the literature I have  
13          seen.

14          And so I haven't formed the  
15          opinion, though, that it's absolutely  
16          every time. My opinion, I think, is  
17          based on the fact that I believe that  
18          there is data to indicate that  
19          exposure occurs, and that with  
20          routine, continual habit, sort of a  
21          habit exposure, that indeed that there  
22          was some migration that occurs.

23          QUESTIONS BY MS. BOCKUS:

24          Q.       And is it fair to say that you  
25          don't have an opinion as to whether that

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1 migration occurs every day, once a week, once  
2 a month?

3 MS. PARFITT: Objection. Form.

4 THE WITNESS: I haven't  
5 formulated my point -- my opinion  
6 quite that way; however, I do believe  
7 that it is something that is going to  
8 happen routinely with exposure. I do  
9 believe that migration is something  
10 that is going on routinely with  
11 application.

12 So with applications, I do  
13 believe that that is, but I can't tell  
14 you that this amount has migrated on  
15 this particular day with this  
16 particular application, no. That --  
17 the data that we have collected is not  
18 there to allow us to do that.

19 QUESTIONS BY MS. BOCKUS:

20 Q. How do you define the word  
21 "routinely" as you're using it in that  
22 answer?

23 A. So that would be the idea of  
24 repeated exposures, you know, within a week,  
25 within a month, within a year. So not --

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1 routine to me would not be -- would not be  
2 applying it once a month one month, waiting  
3 six months, doing it again, and then not  
4 doing it until the next year.

5 Again, it's the idea -- some  
6 people may -- routine may be during the hot  
7 season of the year, they're routinely getting  
8 daily exposures when it's warm, and during  
9 the cold weather not applying. But then the  
10 next year doing -- that's a routine for them  
11 and their habits based on their pattern of  
12 exposure.

13 Again, we know that talc, when  
14 it -- when it migrates and gets into the  
15 body, we have data to show that it is -- it  
16 is able to persist in the body. The fact  
17 that you may have not been exposed for three  
18 months because it was cold doesn't mean that  
19 you -- that that changes the fact that you're  
20 still at risk with additional exposures the  
21 next -- the next time that that habit  
22 becomes -- comes into place.

23 So I think there's multiple  
24 exposure patterns that are possible, but when  
25 I use routine, it's something that people are

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1       doing throughout their -- a period of their  
2       life. And so it would be something that  
3       happens either on a weekly basis for a good  
4       part of the year. I haven't defined it with  
5       a particular number, though, no.

6           Q.       And my question had to do with  
7       out of the number of times a given woman --  
8       or an average woman uses talc, what  
9       percentage of the time does talc make its way  
10      into her reproductive tract?

11          A.       So I don't think that  
12       anybody -- anybody can point to a piece of  
13       data that tells you that, but, again, it's  
14       based upon the anatomy, I would expect there  
15       to be the potential each time it's applied.

16               And on your question on  
17       routine, when I'm talking routine, I'm  
18       looking at not just frequency but also  
19       duration. So when I'm talking about dose,  
20       it's the fact that they do it on a repeated  
21       basis for a number of -- a period of years as  
22       well.

23               That's what the data shows in  
24       the human studies. It's not something,  
25       again, that may have been done routinely for

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1 one year, but it does appear to be something  
2 that's done more -- longer term than that.

3 But we can't give a number. We  
4 have no threshold. We don't know exactly  
5 what that minimum number is.

6 Q. Do you think that the minimum  
7 number is greater than a year?

8 MS. PARFITT: Objection. Form.

9 THE WITNESS: I haven't formed  
10 that opinion, no.

11 QUESTIONS BY MS. BOCKUS:

12 Q. Do you think it's greater than  
13 a month?

14 MR. MEADOWS: Objection.

15 THE WITNESS: Greater than a  
16 month?

17 QUESTIONS BY MS. BOCKUS:

18 Q. Yes.

19 A. One month in their life?

20 Q. One month in their life, where  
21 they're using it every day for a month.

22 A. So I haven't formed that  
23 opinion at this point in time, but I'd say  
24 it's more likely to occur when you do it more  
25 than a month. But I haven't formed an

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1       opinion on a set number, no. I can't --  
2       can't point you a specific number.

3                   I'm not doing case-specific, so  
4       I've not looked at any of those pieces of  
5       information for any given plaintiff.

6           Q.       And I'm just trying to get the  
7       threshold.

8           A.       Uh-huh.

9           Q.       As I understand it, that is  
10      part of a toxicological evaluation, is the  
11      threshold below which there's not an issue.

12                  So I think you've said you  
13      don't know if it's less than a year, but you  
14      think it's more likely than not that it's  
15      greater than one month.

16                  MR. MEADOWS: Objection.

17      QUESTIONS BY MS. BOCKUS:

18           Q.       Is that fair?

19           A.       No, that's not exactly what I'm  
20      saying. I'm saying we don't know the  
21      threshold. So as a result, I'm not of the  
22      opinion that it absolutely can't -- it only  
23      has to be this long.

24                  What I'm saying to you is per  
25      general principles of toxicology and based on

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1 the human data that we have, it indicates  
2 that it's more frequent than just one month,  
3 but I can't tell you that it's absolutely not  
4 possible.

5 That's where -- I do think when  
6 you're talking about those kinds of patterns,  
7 that's a case-specific issue for individuals,  
8 because I think that would have to be  
9 considered for each individual. But  
10 certainly as a toxicologist, I'm using the  
11 words "routine," "repeated," "longer  
12 duration," "chronic exposure." And when I  
13 defined "chronic" earlier, I talked about  
14 years of exposure versus just one month.

15 That would be consistent with  
16 what I have said, yes, but I'm not -- I -- I  
17 certainly don't want to rule out that there  
18 couldn't be somebody out there that could  
19 show something different, because it may very  
20 well be that there are people that you can  
21 identify with the presence of talc in their  
22 ovaries and all of their other case-specific  
23 things that could -- could make that pattern  
24 a -- make someone be able to draw a  
25 case-specific, reliable conclusion.

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1                   But that's not my role. I  
2 don't do case-specific.

3                   Q.       And I am simply trying to get  
4 the parameters of your opinions with regard  
5 to the amount of talc use one would need to  
6 have before you would feel comfortable --  
7 well, that in your opinion would be  
8 sufficient to create a toxic environment.

9                   MR. MEADOWS: Objection.

10                  THE WITNESS: Well, that's a  
11 different question. So toxic  
12 environment could be with a much  
13 shorter time exposure, okay?

14 QUESTIONS BY MS. BOCKUS:

15                  Q.       Right.

16                  A.       So but if you're talking  
17 about -- the opinion that I have formed has  
18 to do with an increased risk of ovarian  
19 cancer. So with that opinion, that's the  
20 description, I believe, I was giving this  
21 morning. It's the idea that the data that  
22 I've seen indicates that my opinion that  
23 perineal use of talc body powder products  
24 increases your risk for ovarian cancer above  
25 that background level that you know exists.

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1                   That opinion is based on data  
2    that is -- is -- the supporting data would  
3    indicate that it has to be a habit, routine,  
4    a chronic exposure. And so as a  
5    toxicologist, I've tried to put that in  
6    context.

7                   I don't know what else to tell  
8    you. That's the opinions I have formed to  
9    date.

10                  Q.       A chronic -- a habit, routine,  
11    a chronic exposure for years?

12                  A.       Well, chronic --

13                   MR. MEADOWS: Objection.

14                   THE WITNESS: -- is defined as  
15    years, typically, by a toxicologist,  
16    and so that's what I -- that's what I  
17    told you.

18    QUESTIONS BY MS. BOCKUS:

19                  Q.       Shifting to your regulatory  
20    opinions, you would agree that Imerys is a  
21    raw material supplier to J&J; is that  
22    correct?

23                   MR. MEADOWS: Objection.

24                   THE WITNESS: I would call them  
25    an ingredient supplier, yes.

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1       QUESTIONS BY MS. BOCKUS:

2           Q.        Okay. An ingredient supplier.

3                   And you agree that Imerys does  
4       not sell any products to the general public,  
5       correct?

6                   MR. MEADOWS: Objection.

7                   THE WITNESS: I don't know  
8                   that's definitely true, but I'm not  
9                   aware that they do.

10      QUESTIONS BY MS. BOCKUS:

11        Q.        And what Imerys supplies to  
12      Johnson & Johnson is not a finished cosmetic  
13      that is ready to be sold on the market,  
14      correct?

15                  MR. MEADOWS: Objection.

16                  MS. PARFITT: Objection.

17                  THE WITNESS: I don't know that  
18                  I can answer that except in the  
19                  context of Johnson & Johnson's baby  
20                  powder, SHOWER TO SHOWER® and Shimmer,  
21                  it's my understanding that Johnson &  
22                  Johnson mixes -- has some fragrance  
23                  added to the talc.

24                  I don't believe Imerys does  
25                  that, but I don't know for sure.

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1                   So based on what I know -- I'm  
2                   telling you what I know, and I would  
3                   call them, again, an ingredient  
4                   supplier, and I would call Johnson &  
5                   Johnson a cosmetic manufacturer.

6                   Does that answer the question?

7     QUESTIONS BY MS. BOCKUS:

8       Q.       It does.

9                   Would you agree that the  
10          minerals that you have identified in your  
11          report, that the documents that you have  
12          seen, would classify their -- to the extent  
13          that they are ever in the powder, that  
14          they're trace ingredients?

15                  MS. PARFITT: Objection.

16                  MR. MEADOWS: Objection.

17                  THE WITNESS: So which  
18          ingredients are you referring to?

19                  So some of the metals, no, are  
20          not trace ingredients.

21                  Are you talking about the --  
22          are you talking about the -- like the  
23          presence of tremolite or the presence  
24          of chrysotile --

25

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1       QUESTIONS BY MS. BOCKUS:

2           Q.       No. No, I'm sorry. I'm  
3       talking about the three metals that you  
4       identify in your report. Those are trace  
5       elements that are -- that are sometimes  
6       detected in the studies of the -- of the  
7       talc.

8           MR. MEADOWS: Objection.

9           THE WITNESS: It's not how I  
10       would say it. I would say they're  
11       heavy metal components that are  
12       naturally occurring within the product  
13       that are sometimes -- sometimes  
14       detectable at levels that are reported  
15       as trace based on the detection limit  
16       within the analysis, but at other  
17       times they're not listed as trace.  
18       They're actually listed with a  
19       specific amount.

20           So that's what -- how I would  
21       define what I call trace. Usually  
22       that's how it will be reported in the  
23       lab, trace, which means below the  
24       limit of quantification, but it's  
25       there. You're detecting it.

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1                   I would agree that -- that  
2                   there are other descriptions of heavy  
3                   metals in the heavy metal literature  
4                   that talk about trace amounts being  
5                   found in -- naturally occurring in  
6                   food, for example, and I agree that  
7                   that does occur. But in the case of  
8                   this product, we actually have  
9                   often -- we actually have a -- a limit  
10                  that is set for acceptability in the  
11                  specification.

12                  And so I would think it's more  
13                  proper to call it a level of the heavy  
14                  metal that is allowable by the purity  
15                  specifications set by the product.  
16                  And sometimes those levels may be  
17                  above, and most of the times those  
18                  levels are below, which is why it's  
19                  cleared. Because I've seen some  
20                  analyses where different products may  
21                  have been, I guess, turned away or  
22                  considered not acceptable based on the  
23                  analysis of certain types of minerals  
24                  or metals.

25

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1       QUESTIONS BY MS. BOCKUS:

2           Q.       Have you seen any studies where  
3 women's blood has reflected the presence of  
4 nickel or cobalt or chromium?

5           MR. MEADOWS: Objection.

6       QUESTIONS BY MS. BOCKUS:

7           Q.       Who are parts of these  
8 studies -- these ovarian cancer studies?

9           MR. MEADOWS: Objection.

10          THE WITNESS: The

11           epidemiological literature you're  
12 asking me?

13       QUESTIONS BY MS. BOCKUS:

14          Q.       Yes, ma'am.

15          A.       It's possible in the Nurses'  
16 Health Study that we can go to that, because  
17 I know they do collect some heavy metal  
18 levels. I've done that for other clients on  
19 other issues.

20                   Most of the others, I doubt  
21 that we have heavy metal levels in blood.  
22 But certainly there are levels of heavy metal  
23 in blood, especially things like lead, for  
24 example, that we have very limited capacity  
25 to eliminate.

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1                   So whether or not you carry  
2 around a significant body burden of a heavy  
3 metal in your blood is somewhat driven by the  
4 exposure pattern you get. It's something  
5 that's commonly -- or can you excrete it  
6 quickly or not. So...

7                   Q.       And are you familiar with any  
8 studies that have suggested that the use of  
9 body powders leads to a heavy burden of  
10 nickel, chromium or cobalt in the blood?

11                  A.       So I have not seen such  
12 analysis done, no, I have not.

13                  Q.       In paragraph 67 of your report,  
14 which is on page 46 -- I'm sorry, on -- oh,  
15 I'm sorry. Paragraph 64, I apologize.

16                  A.       No. No, that's fine.

17                  Q.       It's on page 44.

18                   You cite to two abstracts --

19                  A.       Yes.

20                  Q.       -- one by Fletcher and one by  
21 Fletcher and Saed.

22                   Do you consider these abstracts  
23 to be reliable sources of data?

24                  A.       They're not as reliable at all  
25 as a peer-reviewed article. So there's a

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1 difference in the weight you give an  
2 abstract, absolutely.

3                         However, knowing the papers  
4 that Dr. Saed has actually published in the  
5 peer-reviewed literature, I have -- I have  
6 mentioned them in here because I do believe  
7 that they are -- they are pieces of  
8 information that are highly relevant to some  
9 of the issues raised in other cellular  
10 studies, and so that's why they're here. But  
11 certainly I do not give them the same weight  
12 as in my assessment of overall risk.

13                         And I would say that I had the  
14 same opinions on risk before I had these  
15 studies. Because in my original reports,  
16 obviously, I have gone further than risk and  
17 talked about cause, and I didn't have the  
18 Fletcher studies.

19                         The Fletcher studies are more  
20 on the issue of biologic plausibility and  
21 mechanism versus being important  
22 underpinnings, for example, for a hazard  
23 assessment.

24                         Q.           Is there any way that someone  
25 reading your report could tell that you

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1 attribute less weight to the abstracts by  
2 Saed and Fletcher just by reading your  
3 report?

4 MR. MEADOWS: Objection.

5 THE WITNESS: I don't know if  
6 they could or not. Hopefully they  
7 would based upon where they appear in  
8 the report. They're not cited a lot  
9 of other places, but they certainly  
10 are cited.

11 So that's why I'm here today,  
12 though. You're asking me these  
13 questions; I'm telling you. That's  
14 how I look at these studies. That's  
15 all I can say.

16 I haven't -- I haven't,  
17 certainly, as I've told you, given  
18 things numerical weight throughout my  
19 report.

20 QUESTIONS BY MS. BOCKUS:

21 Q. Looking at paragraph 118...

22 Well, when you were preparing  
23 your report, were you careful with the  
24 language that you used in it to be precise  
25 and accurate?

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1           A.       I attempted to do that. I  
2       can't tell that you there isn't something in  
3       here I've missed. But, yes, I read this  
4       report six or seven times before I finalized  
5       it, trying to make sure that the language I  
6       was using was an accurate reflection of the  
7       opinion I'm expressing.

8                   But it's possible, if you want  
9       to point to something that you want to ask me  
10      about, I can tell you whether or not that was  
11      something that I would change.

12           Q.       So on page 77, paragraph 118 in  
13      the middle of it, you say, "Based on the  
14      knowledge available by the 1950s, talc body  
15      powders manufactured and sold by Imerys and  
16      Johnson & Johnson."

17                   And that's the question that I  
18      have for you.

19           A.       I see what you're saying.

20           Q.       Was Imerys selling anything to  
21      Johnson & Johnson in the 1950s?

22                   MR. MEADOWS: Objection.

23                   THE WITNESS: I'm thinking.

24                   It's possible they did not. That may  
25      be true.

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1       QUESTIONS BY MS. BOCKUS:

2           Q.       Well, and actually --

3           A.       You know what? When I wrote  
4     this sentence, I assumed that they did, but  
5     if that is not true, then certainly this  
6     sentence should be just Johnson & Johnson.

7           Q.       Well, earlier in your report,  
8     in a footnote you indicate that Imerys began  
9     supplying talc to Johnson & Johnson in 1989  
10    or the late 1980s.

11                  Do you remember making that  
12    notation?

13           A.       So let me look. So if that's  
14     an inconsistency, then that should change.  
15     Let me look.

16           Q.       And that's all I want to know,  
17     if it's an inconsistency, should it change.

18           A.       If it is an inconsistency --  
19     certainly if Imerys was not selling talc to  
20     Johnson & Johnson in 19 -- the 1950s, then --  
21     then certainly Johnson & Johnson's products  
22     would not -- would not be affected by Imerys'  
23     activity.

24                  However, if Imerys is selling  
25     talc to anyone that makes a consumer product

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1      in the 1950s, then -- or a precursor company  
2      to Imerys is making talc that's selling for  
3      body powder to somebody other than Johnson &  
4      Johnson, then that opinion would still hold.

5                   So -- but I certainly agree, I  
6      think I -- you're right, I think I have a  
7      statement about the link between the two in  
8      '89. So in that case, then certainly the --  
9      the link here would be related to Johnson &  
10     Johnson's products.

11                Q.        Okay. Yeah.

12                A.        Whether or not -- if they  
13     weren't sourced from Imerys, then that's a  
14     separate duty on a product, not this product.

15                Q.        If you look on the bottom of  
16     page 7, I think you'll see the footnote I was  
17     referencing.

18                   And with regard to your last  
19     answer, you don't have any information as to  
20     whether Imerys existed and, if it did,  
21     what -- who its customers were in 1950s,  
22     correct?

23                A.        I don't believe I do, no.

24                   MS. BOCKUS: I think that's all  
25     that I have. Thank you.

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1                   MR. LOCKE: I've got a few  
2                   questions.

3                   EXAMINATION

4                   QUESTIONS BY MR. LOCKE:

5                   Q.         Doctor, my name's Tom Locke. I  
6                   represent the Personal Care Products Council.  
7                   We met a couple of times before, I think.

8                   A.         I apologize, I don't recall  
9                   your name at least. The face looked  
10                  familiar, though. I apologize.

11                  Q.         I try to maintain a low  
12                  profile.

13                  I have relatively few  
14                  questions. I wanted to ask you overall about  
15                  your opinion.

16                  Would you agree that reasonable  
17                  scientists can disagree with your opinion  
18                  that talc increases the risk of ovarian  
19                  cancer?

20                  A.         I'd say I wouldn't say it quite  
21                  that way. I'd say that I agree that  
22                  scientists can disagree on conclusions they  
23                  draw, depending on the -- depending on the  
24                  way that they have assessed.

25                  So certainly based on a

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1 complete assessment the way I did, then I  
2 would agree that other people could come to a  
3 different conclusion, absolutely.

4 So I think it depends what you  
5 mean by "reasonable scientist." But I would  
6 agree that individuals can look at the same  
7 body of data and, based on their judgment and  
8 experience, based on looking at that same  
9 body of data, could come to a different  
10 conclusion, yes. That's true.

11 Q. You've been involved in this  
12 talc litigation for at least a couple of  
13 years, right?

14 A. Yes.

15 Q. And you know that various  
16 defendants have offered experts who disagree  
17 with your conclusions, right?

18 A. Some of my conclusions, yes. I  
19 don't know that there is somebody that's in  
20 the litigation that does exactly what I do  
21 across all the opinions I've expressed, but,  
22 yes, certain parts of my opinions there are  
23 other experts I'm aware of, yes.

24 Q. Well, they -- you're aware that  
25 there are defense experts who disagree with

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1 your opinion that talc increases the risk of  
2 ovarian cancer; is that correct?

3 A. Yes, I -- I am aware of that  
4 fact.

5 Q. And in your review of the  
6 records that go back or the scientific  
7 materials that go back 35 years or more,  
8 you've seen that there's disagreement  
9 regarding that issue; is that correct?

10 A. So what documents are you  
11 referring to? Are you asking me about a  
12 specific -- just the published medical  
13 literature? Are you asking about documents  
14 like internal company documents, reviews by  
15 others? What are you asking me about?

16 Q. Well, let's focus on the  
17 published medical literature.

18 There are scientists who have  
19 disagreed with your opinion; is that correct?

20 MS. PARFITT: Objection.

21 THE WITNESS: I'm not aware of  
22 a paper in the published medical  
23 literature that has done the exact  
24 assessment I have done.

25 So I am aware of the fact,

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1 however, that there are individual  
2 papers by scientists that, for  
3 example, have concluded that there is  
4 no association between exposure to  
5 talc perineally and ovarian cancer,  
6 yes. Individual papers, I am aware of  
7 that, but that's different than what I  
8 have done.

9 QUESTIONS BY MR. LOCKE:

10 Q. Let me just ask you about what  
11 you were requested to do on behalf of  
12 plaintiff's counsel.

13 Plaintiff's counsel asked you  
14 to provide opinions related to the human  
15 health hazards posed by exposure to talcum  
16 powder products and how those hazards relate  
17 to the regulatory requirements for marketing  
18 cosmetic ingredients and cosmetic products in  
19 the United States; is that correct?

20 MR. MEADOWS: Objection.

21 THE WITNESS: I didn't write  
22 that, but that sounds like an accurate  
23 reflection of what -- what we -- what  
24 I have done at least in parts of my  
25 report, yes.

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1       QUESTIONS BY MR. LOCKE:

2           Q.     Well, if you look at your  
3 report, I think you go to part where you were  
4 asked to provide -- and I just pulled it from  
5 what you said.

6           A.     So I did write it, I apologize.

7       It didn't sound like me.

8           Q.     It started with "to provide  
9 opinions related to the human health hazards"  
10 and so forth, so I just wanted to make sure  
11 we're clear on that.

12          A.     Sure.

13          Q.     So does that sound right in  
14 terms of what you were asked to do?

15          A.     I said I -- certainly those are  
16 the kinds of things that I was definitely  
17 asked to do. I was asked to do two basic --  
18 two basic things, which was having to do with  
19 toxicology and risk assessment, and then a  
20 separate issue related to regulatory  
21 concerns.

22                   So, yes, those are the two  
23 basic, I guess, buckets of information and  
24 documents that I reviewed and opinions I've  
25 expressed, and I think that's consistent with

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1 what I've been doing in the litigation.

2 Q. Okay. As to that second  
3 bucket, the US regulatory requirements for  
4 marketing cosmetic ingredients and products,  
5 that's not relevant to the scientific  
6 question whether talc may cause ovarian  
7 cancer; am I right?

8 A. No. I disagree with that based  
9 on the fact that a company that markets a  
10 cosmetic product is required to do a safety  
11 assessment. And if in that safety assessment  
12 issues relate to cancer or ovarian cancer and  
13 the use of talc, then those two things are  
14 related.

15 But I would agree that -- that  
16 doing a risk assessment like I've done is a  
17 separate issue from doing a safety assessment  
18 for a product, because there's actually even  
19 a lesser standard for an issue of looking at  
20 a safety assessment for a product versus  
21 actually forming the opinion that there is an  
22 increased risk of cancer with exposure to  
23 talc.

24 Q. Now, did IARC in 2006, did it  
25 look at the US regulatory process in

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1 considering whether talc may cause ovarian  
2 cancer?

3 MR. MEADOWS: Objection.

4 THE WITNESS: I don't think I  
5 understand what you mean. It's not a  
6 US regulatory process, no, if that's  
7 what you're asking me.

8 They have a -- they have a  
9 discussion of what the products are,  
10 which is part of the way they're sold.  
11 But I don't think they're discussing  
12 the duty of a company under the  
13 regulatory process, no, that's a  
14 separate issue.

15 QUESTIONS BY MR. LOCKE:

16 Q. So their analysis of whether  
17 talc may cause ovarian cancer, that's  
18 different than the analysis of whether a  
19 company may have a duty, whatever that duty  
20 may be?

21 MR. MEADOWS: Objection.

22 THE WITNESS: It's a different  
23 process, absolutely. IARC is a  
24 separate, independent body that does  
25 an assessment looking at the issue of

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1           cancer hazard and looking at whether  
2           or not there is sufficient evidence to  
3           categorize that hazard, whereas a duty  
4           of a company under the regulatory  
5           situation is broader than just cancer  
6           hazard; it's a whole different thing.  
7           It's what you do internally before you  
8           market a product.  Totally different.

9                 And so certainly when I --  
10          that's why I have separate sections in  
11          my report, and that's why I even  
12          have -- I've had discussions about the  
13          difference between the regulatory  
14          standard for warning versus the  
15          assessment of risk that may be  
16          required in order to start to produce  
17          a -- identify a association or an  
18          increased risk or even if you did a  
19          causation analysis.  Totally different  
20          type of exercise.

21          QUESTIONS BY MR. LOCKE:

22           Q.       Do you first, in that exercise,  
23          look at the scientific issue of whether talc  
24          may cause ovarian cancer?

25           A.       Are you asking me in either of

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1 these exercises?

2 Q. Well, let's say when you're  
3 getting to -- you mentioned the duty to warn.  
4 So if you're looking at the duty to warn, do  
5 you first have to look at does talc cause  
6 ovarian cancer?

7 MR. MEADOWS: Objection.

8 THE WITNESS: That's not the  
9 question you asked. No. I would  
10 argue, based on the regulations, if  
11 you look at the standard, the question  
12 is, is there evidence to indicate that  
13 there is a chance, there is a  
14 potential -- not that it does, but is  
15 there a potential for that type of  
16 hazard to be posed to consumers who  
17 use the product.

18 It's a possibility versus being  
19 a -- I'm taking it beyond possibility  
20 when I'm doing my assessment for  
21 increased risk. And I talked about  
22 that this morning, and I can't  
23 remember her last name. The  
24 Johnson -- I apologize. But I -- with  
25 Johnson & Johnson. I talked about

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1           this is a different assessment and  
2           different standard. It's a much lower  
3           standard on cosmetics for what needs  
4           to be done as far as warning.

5                 Now, when a company comes and  
6           initiates a safety assessment on their  
7           product, before they even think about  
8           what am I going to warn, they should  
9           be doing a comprehensive assessment of  
10          safety based on what's available  
11          publicly, knowing what others have  
12          reported and then what data they've  
13          collected.

14               If they don't have data at all  
15          on the safety of the product, then the  
16          product has to say that. We don't  
17          know. We do not know if this product  
18          is safe. And that's one of the things  
19          that is allowed under FDA -- under FDA  
20          regulations as well.

21               But essentially some -- some  
22          assessment must be done to understand  
23          from the perspective of the company  
24          that this product is safe for  
25          consumers to use as -- under the

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1                   directions of use.

2                   So in the case of this, it  
3                   would be a body powder being used on  
4                   the body surface but also perineally  
5                   because -- because that was an  
6                   exposure pattern that was understood.

7   QUESTIONS BY MR. LOCKE:

8                   Q.        Okay. You described two  
9                   different buckets. They're independent  
10                  assessments; is that correct?

11                  MR. MEADOWS: Objection.

12                  THE WITNESS: Initially that's  
13                  where I started, and now I'm talking  
14                  two different duties. There's a duty  
15                  to warn, but there's first a duty to  
16                  collect information before you market  
17                  it. It's your premarket safety  
18                  assessment.

19   QUESTIONS BY MR. LOCKE:

20                  Q.        Okay. I'm not actually talking  
21                  about the manufacturer's duty. I wanted to  
22                  just first address your scientific analysis.

23                  That's a separate question that  
24                  led you to your opinion on the -- your  
25                  opinion that talc increases the risk of

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1 ovarian cancer, correct?

2 MR. MEADOWS: Objection.

3 THE WITNESS: Yes, that's what  
4 I described. And I thought you were  
5 talking about duty of the company, and  
6 so I apologize. I didn't mean to go  
7 off on a tangent.

8 If you want to focus just on  
9 the risk assessment -- is that what  
10 you want to do? -- that's what I'm  
11 doing.

12 QUESTIONS BY MR. LOCKE:

13 Q. No, I just want to understand,  
14 those are two different things, though,  
15 right?

16 A. Those are two different --  
17 those are two different tasks that I  
18 undertook, yes. I undertook a risk  
19 assessment task to form opinions based on  
20 what I can say about risk, and then I  
21 separately -- and I had done this earlier on  
22 the issue of warnings, looking at what do we  
23 know about the product and whether or not --  
24 and when did we know it, and what should  
25 consumers have been warned about based on the

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1 safety information that was available over  
2 time.

3 Q. The risk assessment task,  
4 that's what you mean by your analysis that  
5 talc increases the risk of ovarian cancer?

6 A. That's correct.

7 Q. You could have stopped at that,  
8 but then you performed an additional task; is  
9 that right?

10 A. Well, actually, no, because the  
11 first task I actually started with was the  
12 regulatory task. When I first started  
13 getting involved in the litigation very --  
14 before I wrote my first report, one of the  
15 first things I was looking at was the issue  
16 of the duty of the manufacturer to provide  
17 warnings.

18 And then after that, I expanded  
19 that role to be an inclusion as well of a  
20 causation analysis.

21 And then now I'm not doing a  
22 full causation analysis in this litigation,  
23 but I'm using essentially some of the same  
24 information to provide you with a description  
25 of a -- a health risk assessment, which was

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1 also sort of -- that's a piece along the way  
2 to doing a causation analysis, but it's not  
3 the same.

4 Q. Your opinion regarding the  
5 FDA's responsibilities and functions, that's  
6 not related to your opinion that talc may  
7 cause an increased risk in ovarian cancer; is  
8 that correct?

9 MR. MEADOWS: Objection.

10 THE WITNESS: I don't think  
11 that's true the way you're asking that  
12 question, because I don't know how you  
13 divorce the fact that as a -- in a  
14 regulatory assessment, if I identify  
15 cancer hazard, I have identified a  
16 duty to warn. That's certainly  
17 something that should be warned about  
18 when I understand that there's not  
19 only the potential, but I believe  
20 there's an increased risk.

21 But I would agree with you that  
22 in my report, I'm laying out for you  
23 even different bodies of information  
24 that -- as I step through it.

25 Does that make sense to you?

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1       QUESTIONS BY MR. LOCKE:

2           Q.       Not really.

3           A.       I'm sorry.

4           Q.       I'm talking about your  
5       scientific analysis here, not your regulatory  
6       analysis.

7                   To do your scientific analysis,  
8       you looked at scientific materials, right?

9           A.       Yes, but I do the same thing  
10      for my regulatory analysis. That's why I'm  
11      confused. I -- to me they are connected.

12                  But I would agree with you, I  
13      had an analysis. Let's just talk about that,  
14      my analysis on risk assessment and my  
15      opinions that I've expressed. Those are laid  
16      out in a separate section of my report,  
17      absolutely. So we could talk about that if  
18      you'd like.

19           Q.       Well, I just want to  
20      understand, and I think I do now, that's a  
21      separate issue from your regulatory opinion?

22           A.       It's not a separate issue.

23      That's where I'm having trouble with your  
24      language.

25                  It's a separate task because,

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1 for example, I may have only been asked, but  
2 I wasn't, to just describe whether or not, as  
3 a human risk assessor and toxicologist, there  
4 is a hazard or a risk posed by the product,  
5 and I could stop there.

6 But I was asked, based on --  
7 based on my experience working in the area of  
8 regulatory toxicology but also on regulatory  
9 issues for clients where I give advice, I was  
10 asked to look at how does that scientific  
11 information impact what the company should be  
12 doing.

13 And so that's -- that's why I'm  
14 saying you can't divorce them, because the  
15 warning issue I'm talking about is intimately  
16 tied into the human health risk assessment  
17 results.

18 Q. So do you consider yourself  
19 primarily here as a warning expert?

20 MR. MEADOWS: Objection.

21 THE WITNESS: I consider that  
22 one of my roles, yes, absolutely.

23 It depends upon how individual  
24 cases, individual attorneys, will --  
25 will ask -- decide to use me. For

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1 example, I have been used in one trial  
2 to only talk about the toxicology.  
3 Other trials, I've talked about  
4 toxicology as well as regulatory  
5 issues. So I think it just depends on  
6 the case.

7 In the MDL, I am prepared,  
8 however, to come to talk at a trial on  
9 the regulatory system that guides  
10 cosmetics as well as provide opinions  
11 that talk about what are the hazards  
12 of talc, what is the toxicology of  
13 talc, what do -- how can you be  
14 exposed to talc, that migration issue,  
15 and then my opinions about whether or  
16 not I believe that there is an  
17 increased risk of ovarian cancer.

18 So I would be -- be prepared to  
19 talk about both of those things.  
20 That's why I said I do think I'm a  
21 little different than some of the  
22 other experts that you may encounter,  
23 for example, in the defense side,  
24 where someone may just do regulatory  
25 or somebody may just do toxicology.

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1           But I practice in both those areas in  
2           my consulting practice and in my  
3           experience.

4       QUESTIONS BY MR. LOCKE:

5           Q.       Let me ask you a few questions  
6       about your cosmetic ingredient review  
7       statements, CIR.

8                   We can agree to call it that,  
9       right?

10          A.       Yes, that's fine.

11          Q.       In parts of your report, you  
12       cite the CIR as an authoritative source on  
13       cosmetic ingredients; is that correct?

14          A.       So where are you looking at,  
15       the background information on the CIR?

16                   Yes, they certainly are a  
17       source of information that FDA relies upon as  
18       far as assessments, yes, that's true.

19          Q.       Well, and on page -- or  
20       paragraph 35, page 23, you cite to the CIR  
21       on, for example, chemicals purportedly in  
22       cosmetics. You have a footnote there.

23          A.       So --

24          Q.       I believe it's footnote 31.

25          A.       Yes, I have looked at -- looked

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1 at the CIR as a source of information because  
2 many of the chemicals, many of the  
3 ingredients within the fragrance of Johnson &  
4 Johnson, the only available information may  
5 be found within the CIR that's publicly  
6 available.

7 Q. And you rely on the report of  
8 Dr. Cralley; is that correct?

9 MR. MEADOWS: Objection.

10 MS. PARFITT: Objection.

11 QUESTIONS BY MR. LOCKE:

12 Q. You reference Appendix D to  
13 your report. I believe if you stay on the  
14 same page you'll see that, the same  
15 paragraph.

16 A. I wouldn't say I rely on the  
17 report of Dr. Cralley because I form my  
18 opinions independent of Dr. Cralley, but  
19 certainly his -- I believe if you go to his  
20 reports, his report is supportive of my  
21 opinions in this area.

22 Q. Did you read his report?

23 A. I have read it now, but I did  
24 not read it before I -- before I formed my  
25 opinions in this particular paragraph, yes.

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1           Q.       I'm a little confused because  
2       you're citing to his report.

3                    You read it or you didn't read  
4       it before you wrote this paragraph?

5           A.        I read it before I wrote the  
6       paragraph. I didn't read it before I had  
7       formed the opinion. Do you understand what  
8       I'm saying?

9                    I did my review of the irritant  
10      chemicals independently before I looked at  
11      Dr. Cralley's report. So I had formed the  
12      opinion that -- of the chemicals I had  
13      searched for that this is what I identified.  
14      And that's what this is talking about, right?

15                  I'm saying here that of the  
16      more than 100 chemicals included, over  
17      70 percent are compounds linked with some  
18      level of irritant hazard. That was done on  
19      my own.

20                  Then, if you go to look at  
21      Dr. Cralley's report, I cite it here because  
22      it's consistent. That is, his report  
23      provides support additionally for the  
24      statement I'm making.

25                  So I'm not relying on his

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1 conclusions to make my opinion, but it's  
2 certainly -- I am citing it here as it being  
3 a piece of evidence that is consistent with  
4 my opinions.

5 Q. Sorry, I seem to have messed up  
6 my microphone. I'll try to hold it for a  
7 little bit then.

8 Do you disagree with  
9 Dr. Cralley's report?

10 A. I have not formed an opinion  
11 that I agree or disagree. He -- with his --  
12 I believe he has information that is  
13 consistent with the opinion I'm expressing in  
14 the sentence, however.

15 Q. And do you know that  
16 Dr. Cralley repeatedly cites to the CIR as an  
17 authoritative source regarding cosmetic  
18 ingredients?

19 A. I don't know that he uses that  
20 exact language, but he does cite to it, yes,  
21 in his report. Certainly he does.

22 Q. More than 20 times, right?

23 A. That, I have not counted. I  
24 can't tell you that. But he does, just like  
25 I do, as a source of information when there

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1 is no other source available.

2 Q. Okay. In your report you state  
3 that the CIR process is administered  
4 independent of the FDA.

5 But the FDA is on the CIR  
6 steering committee; is that correct?

7 A. That is correct.

8 Q. You don't mention that in your  
9 report, although you mention others who were  
10 on the CIR steering committee, correct?

11 A. Yes, there's a paragraph where  
12 I talk about others, yes.

13 Q. But you don't mention that the  
14 FDA is on the steering committee?

15 A. I believe I -- I believe I've  
16 been asked that question before, and I said  
17 yes, but certainly in this report I don't  
18 believe I state that, that is true.

19 Q. CIR solicits input from the  
20 public; is that correct?

21 MS. PARFITT: Objection.

22 THE WITNESS: I would say they  
23 solicit input from industry, yes.

24 QUESTIONS BY MR. LOCKE:

25 Q. Well --

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1           A.       But they -- and they do have a  
2       public comment period, which is mainly input  
3       from industry.

4                   But I agree that they do -- and  
5       if what you're referring to is a public  
6       comment period, yes, there is that for the  
7       documents.

8           Q.       You can go on the website and  
9       see what ingredients CIR is going to review,  
10      right?

11       A.       Yes, you can.

12       Q.       Have you done that?

13       A.       Yes, I've done it many times  
14      before.

15       Q.       Okay. And did you submit  
16      comments on talc in 2012?

17       A.       No, I did not.

18       Q.       Okay. You could -- the public  
19      can submit comments many times during the  
20      process of an ingredient review; is that  
21      correct?

22       A.       There are different --  
23      different stages of the draft document. Is  
24      that what you're asking me? Yes, that can be  
25      done.

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1           Q.       Well, even before it's a draft,  
2 CIR is soliciting information about the  
3 ingredient to include in the initial  
4 materials provided to the expert panel; isn't  
5 that correct?

6           A.       Technically I believe that is  
7 true, but I would disagree that that is  
8 something that happens routinely. But I  
9 would agree that -- I would say technically  
10 you may be -- that is something that could  
11 occur, yes, but that is not the situation,  
12 for example, in the case of talc.

13          Q.       Why not?

14          A.       Based upon what I have seen  
15 described as how the review was done, and  
16 that has to do with the testimony of  
17 different -- or different documents that I've  
18 reviewed and the testimony of individuals  
19 related to this document.

20          Q.       Well, Dr. Cramer could have  
21 submitted comments to the CIR regarding talc,  
22 couldn't he?

23                   MR. MEADOWS: Objection.

24                   MS. PARFITT: Objection.

25                   THE WITNESS: You'd have to ask

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1                   Dr. Cramer if he was aware that they  
2                   were reviewing it. I can't answer  
3                   that for Dr. Cramer.

4                   But if he was aware of it,  
5                   certainly -- if you're aware of the  
6                   process going on and the timing of it,  
7                   certainly you can submit comments.

8                   I'm not disagreeing with you on that.

9                   That is true.

10          QUESTIONS BY MR. LOCKE:

11               Q.       CIR publishes in advance what  
12               it's going to review; isn't that correct?

13               A.       What is coming up for review?

14               Q.       Yes.

15               A.       Yes, things that are proposed  
16               for the next meeting, yes, that's true.

17               Q.       And you could submit comments  
18               to the first draft of the CIR report; isn't  
19               that correct?

20               A.       I would agree that that is  
21               possible to happen, yes.

22               Q.       And you can submit comments  
23               before the final report is drafted, correct?

24               A.       Yes, as long as it's still in  
25               draft form, yes, those comments can be

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1 submitted.

2 Q. And CIR meetings are open to  
3 the public, right?

4 A. That is true, they are open to  
5 the public, but in my experience it -- they  
6 are not meetings that are heavily attended by  
7 the public but indeed are -- tend to be  
8 meetings attended by industry stakeholders  
9 within the ingredients that are being  
10 reviewed.

11 Q. You know Mr. Steinberg here.  
12 He was a plaintiff's expert for a while?

13 A. I don't know him personally,  
14 but I know his name and I know he was a  
15 plaintiff's expert, yes.

16 Q. You know he attended the talc  
17 meeting, right?

18 A. Yes, I believe he was working  
19 with indus -- he works with industry, so I  
20 believe indeed he did attend that meeting.

21 Q. You're not claiming he was  
22 working with any industry member regarding  
23 talc, are you?

24 A. That's not what I stated. I  
25 know he's a consultant to the cosmetic

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1 industry, so it doesn't surprise me. And I  
2 believe he lives in the area, so it doesn't  
3 surprise me that he attended.

4 I haven't spoken to him about  
5 any of that, though, so I have no specific  
6 details of that.

7 Q. Transcripts of the meeting are  
8 available to the public, right?

9 A. You can download the  
10 transcripts, yes.

11 Q. They're on the website?

12 A. That's what I said. You can  
13 download. I'm sorry.

14 Q. Okay.

15 A. Yes, you can download them from  
16 the website.

17 Q. Did you submit comments to the  
18 CIR regarding talc?

19 A. No, I did not.

20 Q. Why not?

21 A. I wasn't aware of the process  
22 that was going on in the draft form at the  
23 time.

24 Q. Why is that?

25 A. I was not following the CIR for

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1      talc at that particular time. I have a lot  
2      of other clients and a lot of other issues  
3      that go on on a routine basis, and I -- I  
4      literally would not have time to follow every  
5      assessment they do, considering that they do  
6      thousands of chemicals.

7            Q.      Did you know of the CIR prior  
8      to your retention by plaintiff's counsel?

9            A.      Yes. In fact, I -- one of the  
10     journals that I receive, International  
11     Journal of Toxicology, maybe, publishes many  
12     of their safety assessments. So I certainly  
13     am, yes.

14            I was aware -- when I was at  
15     Eviron, I was aware of the existence of CIR.

16            Q.      Have you ever provided prior to  
17     this litigation -- and by "this litigation" I  
18     mean any aspect of the talc litigation -- an  
19     expert opinion on cosmetics' ingredients?

20            A.      You're asking me in any other  
21     litigation on a cosmetic ingredient?

22            I'm thinking back to the cases  
23     I've worked on. Not as a -- not as a  
24     testifying expert.

25            At Eviron, though, we worked on

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1 litigation involving cosmetic ingredients,  
2 thought I was not the testifying expert.

3 Q. In your report you talk about  
4 the percentage of -- or the number of  
5 ingredients that the CIR listed as unsafe.

6 Do you recall that?

7 A. Yes. I mean, if you want me to  
8 verify the number, I need to go there. But,  
9 yes.

10 Q. You don't mention that CIR has  
11 put limitations on approximately 50 percent  
12 of the ingredients that it has reviewed, do  
13 you?

14 A. I don't mention that, but they  
15 do. They have -- they have -- when they have  
16 a statement about safety, they will -- they  
17 will often talk about the limitations from  
18 the safe use based on either concentration or  
19 even maybe route of exposure, that is true.

20 Q. Why don't you do that? Why  
21 didn't you include that in your report?

22 A. No particular reason. I mean,  
23 the point I'm trying to make is really the  
24 workload that's going on here and the  
25 impossibility of the task of providing the

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1 same level of review of any of these  
2 ingredients as can be provided -- as was  
3 provided by the IARC.

4 And so, again, that's one of  
5 the comparisons I'm doing. I'm talking about  
6 the difference in the time, the effort, the  
7 difference in the independence of the  
8 reviews. And so that -- when I'm talking  
9 about, those numbers, that's what I'm  
10 focusing on. I'm focusing on the fact that  
11 you have so many reviews in a very short  
12 period of time, with a one-expert panel, it's  
13 impossible for that level of analysis and  
14 review to be anywhere near what IARC panels  
15 do, and also nowhere near the level of review  
16 that I have done based on the number of  
17 documents that I have analyzed and looked at.  
18 So it's a different type of review.

19 Q. Let me ask you a few questions  
20 because you have criticized the panel.

21 You would agree with that,  
22 correct?

23 A. Yes. Oh, absolutely. This  
24 particular analysis I have. I have made some  
25 general criticisms of the overall process,

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1 and then I made some specific criticisms of  
2 this particular review.

3 Q. And one of your criticisms is  
4 that the CIR -- I think you said two CIR  
5 expert panelists had conflicts of interest;  
6 is that correct?

7 A. Yes, that -- they did, that  
8 were not -- that were not -- I believe not  
9 understood even by Dr. Andersen at that time.  
10 I think these are things brought up to him  
11 that he was not aware of.

12 Q. All right. Now, you read his  
13 testimony in one of the trials in California,  
14 right?

15 A. Yes, that's the -- in fact,  
16 that's the source of the information where  
17 I'm citing to those names of those  
18 individuals. I think I refer to that, his  
19 trial testimony.

20 Q. And didn't he, though, say,  
21 well, he didn't view it as a conflict of  
22 interest because the money wasn't going to  
23 them personally, it was going to their  
24 organizations?

25 A. He did make that statement,

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1 yes.

2 Q. And you disagree with that  
3 statement?

4 A. I don't -- I mean, his  
5 testimony is what it is.

6 Are you asking me do I disagree  
7 that that's a conflict of interest?

8 I disagree that you shouldn't  
9 disclose that as a potential conflict in the  
10 documents that are produced, just like I do  
11 when I write an article and I disclose that  
12 I've had funding. I don't say what the  
13 funding specifically paid for, but I've had  
14 funding or support from this industry  
15 individual or that industry individual.  
16 It's -- it's something that just is about  
17 transparency.

18 Q. So when you write articles, you  
19 say that you've been paid a lot of money by  
20 plaintiffs' lawyers?

21 MR. MEADOWS: Objection.

22 MS. PARFITT: Objection.

23 THE WITNESS: Well, I haven't  
24 written an article that overlaps with  
25 an issue that I've addressed in

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1           plaintiffs' litigation, but I  
2           certainly have given my conflict of  
3           interest statements that relate to the  
4           issue in the article.

5           I do that -- I've done that  
6           with -- on my work -- several of my --  
7           several of my assessments talking  
8           about risks of pesticides. I've done  
9           it with the work that I've done that  
10          that's been sort of, I guess,  
11          policy-type work on behalf of the  
12          American Chemistry Council.

13           So absolutely I do.

14          QUESTIONS BY MR. LOCKE:

15          Q.        Okay. You don't think it's  
16          relevant that you receive 50 percent of your  
17          money solely from plaintiffs' products  
18          liability lawyers?

19           MR. MEADOWS: Objection.

20           MS. PARFITT: Objection. Form.

21           THE WITNESS: If it has nothing  
22          to do with the issue that I'm  
23          addressing in the paper, no, I do not  
24          think that.

25           But when you're accepting money

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1                   from an industry or a company that has  
2                   to do with the issue you're looking  
3                   at, yes, a conflict -- a conflict of  
4                   interest absolutely needs to be  
5                   described.

6        QUESTIONS BY MR. LOCKE:

7                   Q.        And that would -- well, let me  
8        just ask you: You're not an ethicist, are  
9        you?

10          A.        No, I'm not trained as an  
11        ethicist.

12          Q.        And you're not a lawyer, are  
13        you?

14          A.        Well, no, but I have passed the  
15        patent bar, but I'm not trained as a lawyer.

16          Q.        That doesn't make you an  
17        ethicist, right?

18          A.        No, it does not.

19          Q.        Okay. Let's talk about one of  
20        the people you criticized, Dr. Wilma  
21        Bergfeld.

22                   Did you know she was the first  
23        woman who was the president -- to be the  
24        president of the American Academy of  
25        Dermatology?

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1           A.       No, I don't know her  
2 personally, so, no, I did not know that.

3           Q.       Did you investigate her at all  
4 when you criticized her?

5           A.       I wasn't criticizing her, I was  
6 criticizing the CIR process for failing to  
7 disclose the conflicts of interest of  
8 individuals that were involved in their  
9 assessment.

10           I certainly am not giving  
11 personal criticism to either of those  
12 individuals.

13           Q.       You would agree that the  
14 American Academy of Dermatology is a  
15 reputable organization?

16           A.       I haven't formed an opinion one  
17 way or the other; however, I'm aware of them,  
18 and certainly I know individuals that are  
19 members of it, yes.

20           Q.       Are those individuals reputable  
21 people?

22           MS. PARFITT: Objection.

23           THE WITNESS: They are people  
24 that practice medicine that certainly  
25 I would go see. I mean, you're asking

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1           me if I formed a very specific opinion  
2           about them as individuals, and I  
3           haven't done that.

4        QUESTIONS BY MR. LOCKE:

5           Q.       Do you have any reason to  
6 believe that the American Academy of  
7 Dermatology is disreputable?

8           A.       No. Again, I haven't formed an  
9 opinion one way or the other. I'm aware of  
10 the organization, and it certainly is one  
11 that is -- has within its members a number of  
12 people that I know that practice in  
13 dermatology.

14          Q.       Did you know that Dr. Bergfeld  
15 was the first woman to be president of the  
16 Cleveland Academy of Medicine?

17          A.       To the what? What was the  
18 first word?

19          Q.       Cleveland Academy of Medicine?

20          A.       No. Again, I'm not aware of  
21 her CV specifically, other than what may have  
22 been discussed -- it's possible her -- I know  
23 her affiliation will be listed in some of the  
24 documents as to where she is today, but I do  
25 not know her CV and her history.

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1 Q. Are you aware that she was the  
2 first president -- or she was a president of  
3 the American Society of Dermatopathology?

4 A. No. Same thing. If I'm not  
5 aware of her CV, I wouldn't know that.

6 Q. How about that she was the  
7 former chair to the FDA's drug -- FDA's  
8 Dermatology and Ophthalmology Advisory  
9 Committee?

10 A. Same answer. I don't know her  
11 CV, so I have no knowledge.

12 Q. Is it your opinion that  
13 Dr. Bergfeld was not qualified to chair the  
14 CIR panel that considered talc?

15 A. I don't think I formed that  
16 specific opinion. Instead, what I have --  
17 the opinions I formed relate to the overall  
18 makeup of the panel that failed to include  
19 individuals with expertise that were -- that  
20 are really key to assessing the safety of  
21 talc. And that had to do with the issues of,  
22 as I discuss it, epidemiology -- oh, I'm  
23 sorry, I think I need to put this back --  
24 period -- sorry. In the area of epidemiology  
25 is one that I talked about it specifically,

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1 and also gynecological -- gynecological  
2 sciences on the issue of migration.

3 Q. You're not a epidemiologist,  
4 are you?

5 A. Not by training. It's a tool I  
6 use all the time, but I'm not an  
7 epidemiologist by training.

8 Q. And panel members on the CIR,  
9 they might have used the same tool that  
10 you're using to form your opinion about talc,  
11 correct?

12 MR. MEADOWS: Objection.

13 THE WITNESS: Based on what  
14 I've reviewed from the minutes and the  
15 write-up, I would disagree that that  
16 is -- they have done -- they've used  
17 the tools in the same way I have. I  
18 disagree with that.

19 QUESTIONS BY MR. LOCKE:

20 Q. No, but I'm saying their  
21 epidemiology could be the same background  
22 that you have. You haven't reviewed who they  
23 are, so you really don't really know.

24 MR. MEADOWS: Objection.

25 THE WITNESS: Well, I do

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1 know -- I do know Dr. Klaassen, who I  
2 believe was on the panel as a  
3 toxicologist. He is not somebody  
4 that -- he is not somebody that I  
5 understand does a significant amount  
6 of evaluation in risk assessment for  
7 epidemiological studies. He has done  
8 some of that, yes, I agree, but it's  
9 different training than mine.

10 QUESTIONS BY MR. LOCKE:

11 Q. You're better qualified than he  
12 is?

13 A. No, that's not what I'm saying.  
14 I'm saying it's different background.

15 The question that I heard you  
16 ask me, I believe, was directed towards the  
17 differences in my background versus somebody  
18 else's.

19 And I'm saying that I'm not  
20 aware that he has the same background I do,  
21 but there is not -- there was not somebody on  
22 the panel that had specific expertise and  
23 analysis of epidemiological studies as an  
24 epidemiologist. And I think that's important  
25 in this case where you're analyzing in a

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1 causation analysis a wide variety of studies.

2 So I do think it's important.

3 Q. You're not a gynecological  
4 oncologist, are you?

5 A. No, I'm not. But again, that  
6 would have been an important expertise to  
7 have on the panel when --

8 Q. And yet you formed your opinion  
9 with --

10 MR. MEADOWS: Hold on.

11 MR. LOCKE: No. No. Go ahead.

12 You can ask follow-up questions  
13 if you want.

14 MR. MEADOWS: You're  
15 interrupting her.

16 MR. LOCKE: Well, I've got a  
17 limited amount of time, and I've got  
18 to keep moving.

19 MR. MEADOWS: Well --

20 MR. LOCKE: They're very long  
21 answers to questions that I'm not  
22 asking. So I -- you follow up if you  
23 would like with your questions, but I  
24 got to keep moving.

25 MR. MEADOWS: Well, I'm sorry,

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1           but you're not going to be allowed to  
2           interrupt her.

3                   MR. LOCKE: Okay. Then we'll  
4           go longer. If she's going to answer  
5           questions I'm not asking, then I need  
6           to go -- I need to be able to go  
7           longer.

8                   MR. MEADOWS: You're not going  
9           to be allowed to interrupt her.

10                  That's just the bottom line.

11          QUESTIONS BY MR. LOCKE:

12                  Q.        You're not a gynecological  
13           oncologist, right?

14                  A.        I'm not trained as a  
15           gynecologic oncologist, that is true.

16                  Q.        You're not a medical doctor,  
17           correct?

18                  A.        I am not a physician, that is  
19           correct.

20                  Q.        Let's talk about the citizens  
21           petition.

22                          The FDA frequently seeks  
23           scientific information from cosmetic  
24           manufacturers; is that correct?

25                  A.        First part of the question?

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1 I'm sorry.

2 Q. The FDA frequently seeks  
3 information, scientific information, from  
4 cosmetic manufacturers; is that correct?

5 A. I don't understand what you  
6 mean by "frequently seeks." They rely on  
7 cosmetic manufacturers to do their own safety  
8 assessments.

9 Is that what you're referring  
10 to?

11 Q. Well, they ask PCPC to comment  
12 on scientific issues, correct?

13 A. Yes, I would agree that that  
14 interaction has happened, but that's not  
15 where the responsibility lies. But I agree,  
16 they have.

17 Q. I'm not asking about  
18 responsibility. I'm asking: Has the FDA  
19 asked cosmetic manufacturers for scientific  
20 information?

21 A. Yes, they have in this case. I  
22 discuss some of that, yes.

23 Q. And they do that frequently,  
24 right? Not just in this case, but generally?

25 A. I can't answer that for all

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1 situations. I have seen it happen before,  
2 yes.

3 Q. The FDA asked, for example, for  
4 then CTFA to cosponsor the 1994 workshop on  
5 talc, correct?

6 A. Yes, they did.

7 Q. The FDA knew that the report  
8 prepared by Dr. Huncharek and Dr. Muscat was  
9 based on PCPC's retention of those  
10 consultants, correct?

11 A. So what are you -- what time  
12 period are you talking about?

13 Q. Well, now, there was only one  
14 time that Drs. Huncharek and Muscat submitted  
15 a report to the FDA regarding talc, correct?

16 A. So I need to look to confirm  
17 that. Which time period are you talking  
18 about?

19 Q. 2009. Citizens petition.

20 A. Oh, that is true. In the  
21 citizens petition, that is true, yes. But  
22 I -- but...

23 Q. I mean, it says in the letter,  
24 "We're submitting a report written by Drs.  
25 Huncharek and Muscat," correct?

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1           A.       In the cover letter from the  
2 CRE?

3           Q.       From -- not CRE, from PCPC.

4           A.       Okay. So let -- I need to -- I  
5 need to refresh my memory on the way the  
6 submissions were made. I apologize.

7                   Do you remember which paragraph  
8 that you're referring to?

9           Q.       Well, it's throughout your  
10 report you're talking about the citizens  
11 petition.

12          A.       So it's my recollection, based  
13 upon the documents that I have seen, that it  
14 was not a transparent process at all times  
15 that Drs. Huncharek and Muscat were being  
16 identified as independent consultants and  
17 were not ones that were being actually paid  
18 by the industry for some of the work that  
19 they did. And I think that's discussed in my  
20 report.

21          Q.       Well, let's break that down.

22          A.       If you want me to confirm the  
23 issue of the 2009 -- if you will point me to  
24 where you say I discuss this, I will confirm  
25 that or not.

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1 Q. Well, let me break it down.

2 Citizens petition submitted in  
3 2008, right?

4 A. Well, there were two: one in  
5 1994 and another -- I'm sorry, 1992, and  
6 another in 2008.

7 Q. Well, there are actually  
8 several more than that, but let's just focus  
9 on the 2008.

10 In 2008, a citizens petition  
11 was submitted?

12 A. Yes, that is true.

13 Q. And PCPC responded to that  
14 citizens petition in 2009, correct?

15 A. They submitted comments. Is  
16 that what you're asking me? Yes, they did.

17 Q. Yes.

18 And that was a cover letter,  
19 correct?

20 A. A cover letter -- that's all it  
21 was was a cover letter?

22 Q. Well, attached to the cover  
23 letter was a report from Drs. Huncharek and  
24 Muscat?

25 A. Yes, that is true.

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1 Q. And you're not aware of any  
2 other document indicating that PCPC ever  
3 hired Drs. Huncharek or Muscat?

4 A. So that's where I'll need to go  
5 back and look at the documents, because --  
6 that I have discussed. So I need to find  
7 that on my paragraph.

8 If you want to go off the  
9 record for a minute so I don't waste your  
10 time, I will look.

11 Q. Sure.

12 A. It's up to you. Or we can stay  
13 on the record.

14 MR. LOCKE: I'm fine going off.

15 VIDEOGRAPHER: We are going off  
16 the record at 4:23 p.m.

17 (Off the record at 4:23 p.m.)

18 VIDEOGRAPHER: We are back on  
19 the record at 4:25 p.m.

20 QUESTIONS BY MR. LOCKE:

21 Q. The question I asked: Are you  
22 aware of any other document indicating that  
23 PCPC ever hired Dr. Huncharek and Muscat  
24 other than for the 2009 response or  
25 submission to the citizens petition?

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1                   A.         I would have to pull this  
2 document, but in paragraph 90 I make a  
3 statement: A 2005 response written by  
4 Dr. Muscat says -- this is not '09, this is  
5 2005, and Dr. Huncharek critiqued the work of  
6 Dr. Cramer, who also failed to disclose the  
7 financial relation -- I'll start over.

8                   Okay. So I'm sorry to repeat  
9 myself, but there was a little noise.

10                  You asked 2009. So the other  
11 time period I have in my report in  
12 paragraph 90 talks about 2005, but I'd have  
13 to pull this document.

14                  But I am citing to the  
15 deposition of Dr. Loretz, who was a PCPC  
16 employee, so I think I would need to pull  
17 this in order to confirm.

18                  But I see depositions of her  
19 and Dr. Nicholson as talking about them  
20 failing to disclose the financial  
21 relationship between their work and industry.

22                  Q.         So if Dr. Loretz did not  
23 testify that PCPC had retained Drs. Huncharek  
24 and Muscat in 2005, you'd have no other  
25 evidence?

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1           A.       I can't answer that  
2     definitively, but this is what I would point  
3     you to. So I'd have to pull these documents  
4     to confirm, but I have -- both paragraphs 89  
5     and 90 address these general issues for you,  
6     but I think that's the sentence and the  
7     documents that I think would be relevant.  
8     But I'd have to pull them to fully answer  
9     your question.

10           Q.       The reason I ask the question  
11    is because you frequently say "the cosmetics  
12    industry" without identifying a party or a  
13    person. And -- well, I'll just leave it at  
14    that.

15           A.       And I guess the reason I'm  
16    saying I need to -- I'm questioning that it  
17    doesn't have to do with PCPC is because I am  
18    citing to a deposition of their employee. So  
19    I need to -- I would -- to affirm it, though,  
20    I'd need to -- I don't want to say that  
21    100 percent the answer to your question is  
22    this is the evidence, but I believe that I  
23    would need to go here to confirm one way or  
24    the other. But certainly I would -- this  
25    raises suspicion about that for me.

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1 Q. You have no evidence that PCPC  
2 ever retained the Center for Regulatory  
3 Effectiveness; is that correct?

4 A. I believe my evidence is hiring  
5 through Imerys, but let me look to make sure  
6 that is true.

7 Q. Why don't you look at page --  
8 or I'm sorry, paragraph 95, page 63.

9 A. That's where I am. That's  
10 where I am, so let me read what I have here  
11 because it's been a while since I've read  
12 this paragraph.

13 So the question is, do I have  
14 in evidence this paragraph that PCPC directly  
15 hired the CRE?

16 No, that is not provided by  
17 this paragraph.

18 Q. Okay.

19 A. However, in this paragraph,  
20 based on these documents that I'm seeing and  
21 I'm -- my memory of what is discussed,  
22 certainly I believe PCPC would have been  
23 aware of the interaction of CRE at these time  
24 points when I'm talking about this event --  
25 these events.

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1                   Q.         What evidence do you have of  
2     that?

3                   A.         Based upon the close  
4     interaction between PCPC, Imerys and Johnson  
5     & Johnson throughout these time periods when  
6     different actions were being taken to comment  
7     or to submit information on behalf of  
8     industry.

9                   Q.         Do you have a single document  
10    you can point to or is that an assumption?

11                  A.         That is something I seem to  
12    remember based on my review of these  
13    documents, but if you need a document, I  
14    would have to -- have to go and look for it.

15                  Q.         Sitting here today, you can't  
16    recall?

17                  A.         I can't give you a specific  
18    document as I sit here today, no.

19                  MR. LOCKE: I have no further  
20    questions.

21                  MR. MEADOWS: Yeah, short  
22    break. Maybe we're done, maybe we're  
23    not.

24                  VIDEOGRAPHER: We are going off  
25    the record at 4:30 p.m.

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1 (Off the record at 4:30 p.m.)

2 VIDEOGRAPHER: We are back on  
3 the record at 4:45 p.m.

4 CROSS-EXAMINATION

5 QUESTIONS BY MS. PARFITT:

6 Q. All right. Dr. Plunkett, good  
7 afternoon. I know it's been a long day.

8 Dr. Plunkett, you were asked  
9 throughout the course of the day about  
10 different constituents which are part of the  
11 talcum powder products.

12 Do you recall those questions?

13 A. Yes.

14 Q. All right. If -- without going  
15 through each and every one of different  
16 constituents that we've talked about that are  
17 contained or could be contained in the talcum  
18 powder products, if they are present, do  
19 those various constituents present and  
20 provide biologically plausible evidence that  
21 talcum powder products can increase the risk  
22 of ovarian cancer?

23 MS. BOCKUS: Object to the  
24 form.

25 THE WITNESS: Yes, which is --

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1 I think I have a couple of paragraphs  
2 where I talk about that issue. It has  
3 to do -- there's other information as  
4 well, but that is a key piece of that  
5 information. And I focused on mode of  
6 action and additivity. That's on  
7 mechanism, biologic plausibility.

8 So the fact that you have a  
9 variety of constituents that have a  
10 known cancer hazard that share a mode  
11 of action, that increases your  
12 confidence in the biologic  
13 plausibility of that relationship  
14 between ovarian cancer and exposure to  
15 talc body powders, yes.

16 MS. PARFITT: Thank you. I  
17 have no further questions. Thank you  
18 very much, Dr. Plunkett. And a happy  
19 holiday to you.

20 THE WITNESS: Thank you.

21 MS. BRANSCOME: I have no  
22 questions.

23 MS. BOCKUS: No questions.

24 VIDEOGRAPHER: The time now is  
25 4:47 p.m. This concludes the

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1 deposition, and we are going off the  
2 record.

3 (Deposition concluded at 4:47 p.m.)

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CERTIFICATE

2

3

I, CARRIE A. CAMPBELL, Registered Diplomate Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, Laura Plunkett, Ph.D., DABT was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

4

5

6

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

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CARRIE A. CAMPBELL,  
NCRA Registered Diplomate Reporter  
Certified Realtime Reporter  
California Certified Shorthand  
Reporter #13921  
Missouri Certified Court Reporter #859  
Illinois Certified Shorthand Reporter  
#084-004229  
Texas Certified Shorthand Reporter #9328  
Kansas Certified Court Reporter #1715  
Notary Public

Dated: 12/20/18

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1                   INSTRUCTIONS TO WITNESS

2

3                   Please read your deposition over  
4       carefully and make any necessary corrections.

5       You should state the reason in the  
6       appropriate space on the errata sheet for any  
7       corrections that are made.

8                   After doing so, please sign the  
9       errata sheet and date it. You are signing  
10      same subject to the changes you have noted on  
11      the errata sheet, which will be attached to  
12      your deposition.

13                  It is imperative that you return  
14      the original errata sheet to the depositing  
15      attorney within thirty (30) days of receipt  
16      of the deposition transcript by you. If you  
17      fail to do so, the deposition transcript may  
18      be deemed to be accurate and may be used in  
19      court.

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1                   ACKNOWLEDGMENT OF DEPONENT

2

3

4                   I, \_\_\_\_\_, do

5                   hereby certify that I have read the foregoing  
6                   pages and that the same is a correct  
7                   transcription of the answers given by me to  
8                   the questions therein propounded, except for  
9                   the corrections or changes in form or  
10                  substance, if any, noted in the attached  
11                  Errata Sheet.

12

13

14

15

Laura Plunkett, Ph.D., DABT                   DATE

16

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Subscribed and sworn to before me this  
\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_.

My commission expires: \_\_\_\_\_

Notary Public

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ERRATA

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3 PAGE LINE CHANGE/REASON

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LAWYER'S NOTES  
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